DEPARTMENT OF HEALTH AND HUMAN SERVICES
OFFICE OF INSPECTOR GENERAL
WASHINGTON, DC 20201

[*We redact certain identifying information and certain potentially privileged, confidential, or proprietary information associated with the individual or entity, unless otherwise approved by the requestor.*]

Issued: December 31, 2012

Posted: January 7, 2013

[Name and address redacted]

Re: OIG Advisory Opinion No. 12-22

Dear [Name redacted]:

We are writing in response to your request for an advisory opinion regarding an arrangement in which a hospital pays a cardiology group compensation that includes a performance bonus based on implementing certain patient service, quality, and cost savings measures associated with procedures performed at the hospital's cardiac catheterization laboratories (the "Arrangement"). Specifically, you have inquired whether the Arrangement constitutes grounds for the imposition of sanctions arising under: (i) sections 1128A(b)(1)–(2) of the Social Security Act (the "Act"), the civil monetary penalty for a hospital's payment to a physician to induce the reduction or limitation of services to Medicare or Medicaid beneficiaries under the physician's direct care; or (ii) the exclusion authority at section 1128(b)(7) of the Act or the civil monetary penalty provision at section 1128A(a)(7) of the Act, as those sections relate to the commission of acts described in section 1128B(b) of the Act, the Federal anti-kickback statute.

You have certified that all of the information provided in your request, including all supplemental submissions, is true and correct and constitutes a complete description of the relevant facts and agreements among the parties.

In issuing this opinion, we have relied solely on the facts and information presented to us. We have not undertaken an independent investigation of such information. This opinion is limited to the facts presented. If material facts have not been disclosed or have been misrepresented, this opinion is without force and effect.

Based on the facts certified in your request for an advisory opinion and supplemental submissions, we conclude that: (i) although the Arrangement could constitute an improper payment to induce the reduction or limitation of services pursuant to sections 1128A(b)(1) – (2) of the Act, the Office of Inspector General ("OIG") will not impose sanctions on [name redacted] in connection with the Arrangement; and (ii) although the Arrangement could potentially generate prohibited remuneration under the anti-kickback statute if the requisite intent to induce or reward referrals of Federal health care program business were present, the OIG will not impose administrative sanctions on [name redacted] under sections 1128(b)(7) or 1128A(a)(7) of the Act (as those sections relate to the commission of acts described in section 1128B(b) of the Act) in connection with the Arrangement. This opinion is limited to the Arrangement and, therefore, we express no opinion about any ancillary agreements or arrangements disclosed or referenced in your request for an advisory opinion or supplemental submissions.

This opinion may not be relied on by any persons other than [name redacted], the requestor of this opinion, and is further qualified as set out in Part IV below and in 42 C.F.R. Part 1008.

I. FACTUAL BACKGROUND

[Name redacted] ("Requestor") is a large, rural acute care hospital located in a medically underserved area in [town, state redacted] ("the Town"). Requestor operates four cardiac catheterization laboratories (the "Labs"), all of which are located in Requestor's main building on its campus. Requestor operates the only cardiac catheterization laboratories within a fifty-mile radius of its campus. Requestor bills for and collects all non-professional fees generated for services provided in the Labs. Requestor provides space, certain non-physician staff, equipment and supplies for the Labs. Requestor certified that the Labs are operated as a provider-based department of Requestor's hospital, in accordance with 42 C.F.R. § 413.65.

Requestor entered into a cardiac catheterization co-management agreement (the "Management Agreement"), with [name redacted] (the "Group") for a term of three years. The Group consists of approximately eighteen full-time physicians, including general cardiologists, interventional cardiologists, and electrophysiologists. Six interventional cardiologists who are members of the Group perform procedures in the Labs. The Group bills Medicare Part B and other payors for cardiology services rendered by its physicians. The Group is the only cardiology group on Requestor's medical staff and the only physician group in the Town that provides cardiac catheterization services.[1]

[1] The Arrangement is not exclusive. If additional cardiologists were to join Requestor's medical staff, Requestor would consider including those individuals within the Arrangement.

The Group does not provide cardiac catheterization services at any location other than the Labs. The Group refers patients to Requestor for inpatient and outpatient procedures, in addition to the cardiac catheterization procedures.

Under the Management Agreement, the Group provides management and medical direction services for Requestor's Labs in exchange for a co-management fee comprised of two components: (1) a guaranteed, fixed payment equal to [amount redacted] per year (the "Fixed Fee"), and (2) a potential annual performance-based payment equal to a maximum of [amount equal to Fixed Fee redacted] per year (the "Performance Fee"). Requestor pays an installment of the Fixed Fee and an estimated installment of the Performance Fee to the Group quarterly. Every year, Requestor reconciles the quarterly installment payments of the Performance Fee under the Arrangement.[2]

Payment under the Arrangement is made by Requestor to the Group. Requestor certified that the Group has agreed that, to the extent revenue derived from the Arrangement results in dividends payable to the Group's shareholders, the Group distributes such dividends based on each shareholder's *pro rata* share of ownership, and that distributions have no relation to an individual physician's participation in the Arrangement.

In exchange for the Fixed Fee and Performance Fee, the Group performs the following duties under the Management Agreement: overseeing Lab operations; providing strategic planning and medical direction services; developing Requestor's cardiology program; serving on medical staff committees; providing staff development and training; providing credentialing for Lab personnel; recommending Lab equipment, medical devices, and supplies; consulting with Requestor regarding information systems; providing assistance with financial and payor issues; and providing public relations services.

The Performance Fee consists of the following components: Requestor's employee satisfaction ("Employee Satisfaction Component"), 5%; patient satisfaction with Requestor's Labs ("Patient Satisfaction Component"), 5%; improved quality of care within the Labs ("Quality Component"), 30%; and implementation of certain measures to reduce costs attributable to Lab procedures ("Cost Savings Component"), 60%. Requestor selected performance measures within these components based on its financial, purchasing, employee satisfaction, patient satisfaction, and quality measurement data systems, as well as certain national cardiology quality measures.

Most measures within the Performance Fee components incorporate three possible achievement levels that trigger payment. If the Group fails to achieve the lowest, baseline achievement level for a measure within a component, it receives no payment for

[2] In the event that the annual reconciliation shows that the Group received a Performance Fee that exceeds the amount it earned, the Group will refund any excess to Requestor.

that measure. The baseline achievement level for any measure reflects improvement over Requestor's *status quo* performance for that measure prior to the effective date of the Agreement. If the Group meets the baseline achievement level for a measure within a Performance Fee component, it receives 50% of the total compensation available for that measure; if it meets the middle benchmark, it receives 75%; and if it achieves the highest benchmark, it receives 100%.

To obtain the portion of the Performance Fee allocable under the Employee Satisfaction Component, the Group must receive a rank between 94.5th–96th percentile as compared to other hospitals surveyed nationally following a bi-annual employee opinion survey of Requestor's employees, performed by Requestor.

To obtain the portion of the Performance Fee allocable under the Patient Satisfaction Component, the Group must meet the following measures on behalf of the Labs:

- Labs must be ranked at the 96th percentile in an annual independent patient satisfaction survey.[3]
- Group physicians must start the first Lab surgical case each day by 8:15 a.m., at least 85% of the days the Lab operates.
- The Group must reduce the time a physician spends between surgical cases in Labs to 25 minutes or less in at least 50% of cases.

To obtain the portion of the Performance Fee allocable under the Quality Component, the Labs must improve their performance as measured by standards promulgated by the Joint Commission, the Centers for Medicare and Medicaid Services ("CMS"), the American College of Cardiology (the "ACC"), and the National Cardiovascular Data CathPCI® Registry (the "NCDR")[4], each of which develops national cardiology quality measures for hospitals. Requestor's performance is measured against hospitals' performance nationally and given a percentile ranking.[5] These standards are subject to revision and update to reflect the appropriate standard of care and currently consist of the following:

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[3] The ranking is based on an independent survey analysis that compares Requestor's patient satisfaction survey data with survey data from a proprietary database of hospitals nationwide.

[4] The NCDR is a cardiovascular data repository developed by the ACC.

[5] Requestor used standards published in the Specifications Manual for National Hospital Quality Measures, Version 4.1 (the "Manual") to establish certain measures within the Quality Component. The Manual is published by the Joint Commission (formerly the Joint Commission on Accreditation of Health Care Organizations) and represents the joint efforts of CMS and the Joint Commission to publish a uniform set of national hospital quality measures. See http://www.jointcommission.org/specifications_manual_

- Reduce "door to balloon time" so that at least 85% of Lab patients' "door to balloon" time is below 90 minutes.[6]
- Prescribe a Beta blocker at discharge[7] to rank between the 70th and 90th percentile of hospitals measured.
- Prescribe an ACE-1 or ARB for left ventricular systolic dysfunction at discharge[8] to rank between the 70th and 90th percentile of all hospitals measured.
- Prescribe an Aldosterone blocking agent at discharge[9] to rank between the 70th and 90th percentile of hospitals measured.
- Document LDL-c level in hospital record[10] to rank between the 70th and 90th percentile of hospitals measured.
- Reduce occurrence of Percutaneous Coronary Intervention complications[11] to a level between 1.4% and 1.7% of patients.
- Reduce the incidence of bleeding in Lab patients within 72 hours of surgery[12] to a level between 0.9% and 1.1% of patients.
- Reduce Percutaneous Intervention Risk Adjustment Complications Index[13] to between 1.25% and 0.96% of patients.

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for_national_hospital_inpatient_quality_measures.aspx.

[6] For this measure, Requestor selected a published guideline set forth in the Manual and adopted by the ACC for measuring the time between a patient's entry to the Emergency Department, when experiencing a heart attack, and the time the physician opens the blocked vessel.

[7] For this measure, Requestor selected a published guideline set forth in the Manual and the ACTION Registry®-GWTG™, which is part of the NCDR. According to Requestor, a Beta blocker is a medication prescribed at discharge that reduces heart rate and blood pressure by dilating blood vessels.

[8] For this measure, Requestor selected a published guideline set forth in the Manual and the ACTION Registry®-GWTG™.

[9] For this measure, Requestor selected a published guideline set forth in the ACTION Registry®-GWTG™.

[10] For this measure, Requestor selected a published guideline set forth in the ACTION Registry®-GWTG™.

[11] For this measure, Requestor selected a published guideline adopted by the ACC, as set forth in the NCDR.

[12] For this measure, Requestor selected a published guideline adopted by the ACC, as set forth in the NCDR.

To obtain the portion of Performance Fee allocable under the Cost Savings Component, the Group must reduce the cardiac catheterization costs per case from [amount redacted] to an amount ranging from [amount redacted] to [amount redacted] per case; and average contrast costs per case from [amount redacted] to an amount ranging from [amount redacted] to [amount redacted] per case. Similar to the other components of the Performance Fee, if the Group meets the baseline achievement level for the cost savings measure, it receives 50% of the total compensation available for that measure; if it meets the middle benchmark, it receives 75%; and if it achieves the highest benchmark, it receives 100%.

Requestor certified the following information. It bases purchasing decisions on the best interests of patient care and utilizes products that are clinically safe and effective. An Interventional Cardiology Committee consisting of all interventional cardiologists who utilize the Labs generates initial product recommendations. It selects products and supplies following a review of evidence-based medicine, empirical trial data, and proven effectiveness. Performance standards drive selection of supplies and equipment in the Labs.

Requestor further certified as follows. It collaborated with the Group's physicians to reduce cardiac catheterization costs by contracting with a single vendor for drug-eluting and bare metal stents, from whom they obtained a highly competitive price. Cost savings also are achieved through better management of the usage of coronary stents and product standardization. Unique-sized stents or other types of drug-eluting stents remain available upon request by an interventional cardiologist, and no physician is ever prohibited from requesting a particular device or supply required to address a patient's unique health needs. Unless otherwise clinically indicated, the Group's physicians adhere to clinical guidelines developed by the ACC regarding the use of bare metal rather than drug-eluting stents. The parties also reduce costs by implementing better management practices with other devices, items, and supplies. For example, Requestor purchases frequently used supplies directly from manufacturers to obtain a better price, and adjusts supply stock levels to reduce shipping costs. The parties also reduce wasted supplies by evaluating necessary items and supplies used during cardiac catheterization procedures and restricting certain items for use only "as needed" during a procedure.

Additionally, Requestor certified that the Group receives [amount redacted] as part of the annual Performance Fee, subject to the aggregate Performance Fee cap, if Requestor

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[13] For this measure, Requestor selected a published guideline adopted by the ACC, as set forth in the NCDR.

achieves a designation as one of Thomson Reuters Top 50 Cardiovascular Hospitals for that year.[14]

Requestor certified that it and the Group's physicians protect against inappropriate reductions in services in the following ways. A team of Requestor's medical staff, including members of the Group, the nurse manager, and administrative leadership, developed the cost savings measures based on evidence and clinical outcomes. The team based product standardization decisions on clinical outcomes ascertained through reviews of clinical studies and documented clinical outcomes.[15] Requestor obtained an independent, third-party valuation regarding the Fixed Fee and Performance Fee paid under the Arrangement. According to Requestor, both the Fixed Fee and the potential Performance Fee are consistent with fair market value and are commercially reasonable. We rely on Requestor's fair market value certification in issuing this opinion.

Requestor uses an independent, third-party utilization review firm to annually review data related to the components of the Performance Fee as well as the clinical appropriateness of the cardiac catheterization procedures performed at the Labs. This firm also annually reviews the Group's performance under the Arrangement to confirm that the Arrangement does not adversely impact patient care. Requestor certified that implementation of the Arrangement has not adversely affected patient care.

Under the Arrangement, all commercially available stents and balloons are available as needed. A Group physician may use the device or supply he or she determines to be most clinically appropriate for each patient. Moreover, receipt of any part of the Performance Fee under the Arrangement is conditioned upon the Group's physicians not taking any of the following actions: 1) stinting on care provided to Requestor's patients; 2) increasing referrals to Requestor; 3) cherry-picking healthy patients or those with desirable insurance for treatment in the Labs; or 4) accelerating patient discharges.

To monitor the Group's performance under the Arrangement, Requestor uses several approaches. First, Requestor's internal audit department reviews all supporting data and

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[14] See Thomson Reuters Top 50 Cardiovascular Hospitals *available at* http://100tophospitals.com/top-cardio-hospitals/. Requestor has not received this designation for a number of years. If the Group achieves the top achievement level for all performance measures, it earns the maximum annual Performance Fee and receives no additional compensation for this top hospital designation.

[15] Members of both Requestor's and the Group's leadership jointly evaluate supply, equipment, and purchasing decisions. The Group participates in evaluation and selection of medical supplies and equipment used in the Labs and evaluates, advises, and assists Requestor in the vendor negotiation process.

documentation related to the Quality and Cost Savings Components. An independent accounting firm then reviews the internal audit department's findings. The firm reports its independent findings to Requestor's compliance officer, who reports to Requestor's Board of Directors. Requestor's Board of Directors' Compliance and Audit Committee reviews the independent accounting firm's findings and approves payment of any amount under the Performance Fee.

Requestor also uses multiple hospital committees to monitor performance of the Group under the Arrangement. The Performance Monitoring Committee, consisting of key hospital management and Lab staff, provides direct oversight to ensure that stinting on patient care, patient cherry-picking, and other improper practices do not occur. Requestor's Credentials and Peer Review Committee monitors and reports on the quality of care provided by the Group and performs peer case review. This committee reports its results to the Medical Executive Committee of the Medical Staff and the Board of Directors' Quality Standards Committee.[16] Also, Requestor's Best Practices Utilization Review Committee, led by physicians on Requestor's medical staff, reviews quality assurance and utilization of the Labs.[17]

Patients and their families are notified in writing of the existence of the Arrangement and their physician's participation in the Arrangement prior to performance of a Lab procedure and concurrent with obtaining the patient's consent to the procedure.

II. LEGAL ANALYSIS

Incentive compensation arrangements like the Arrangement are designed to align incentives by offering physicians compensation in exchange for implementing strategies to meet quality, service, and cost savings targets. However, like any payment arrangement between a hospital and physicians who refer business to the hospital, payments purportedly intended to encourage quality improvements and cost savings might be misused by unscrupulous parties to induce limitations or reductions in care or to disguise kickbacks for Federal health care program referrals. Therefore, such arrangements must be evaluated in light of applicable Federal statutes and the potential for abuse.

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[16] The Board of Directors' Quality Standards Committee monitors the overall quality of care provided by Requestor.

[17] No opinion is expressed or implied in this advisory opinion regarding the liability of any party under the False Claims Act or other legal authorities for any improper billing, claims submission, cost reporting, or conduct directly or indirectly related to the Arrangement.

Properly structured, arrangements that compensate physicians for achieving hospital cost savings can serve legitimate business and medical purposes. Specifically, properly structured arrangements may increase efficiency and reduce waste, thereby potentially increasing a hospital's profitability. However, such arrangements can potentially influence physician judgment to the detriment of patient care. Our concerns include, but are not limited to, the following: (i) stinting on patient care, (ii) "cherry picking" healthy patients and steering sicker (and more costly) patients to hospitals that do not offer such arrangements, (iii) payments to induce patient referrals, and (iv) unfair competition among hospitals offering incentive compensation programs to foster physician loyalty and to attract more referrals.

Hospital cost-savings programs in general, and the Arrangement in particular, may implicate at least three Federal legal authorities: (i) the civil monetary penalty for reductions or limitations of services provided to Medicare and Medicaid beneficiaries, sections 1128A(b)(1)–(2) of the Act; (ii) the anti-kickback statute, section 1128B(b) of the Act; and (iii) the physician self-referral law, section 1877 of the Act.[18] We address the first two of these authorities; section 1877 of the Act falls outside the scope of the OIG's advisory opinion authority. We therefore express no opinion on the application of section 1877 of the Act to the Arrangement.

A. The Civil Monetary Penalty, Sections 1128A(b)(1)-(2) of the Act

Sections 1128A(b)(1)–(2) of the Act (the "CMP") establish a civil monetary penalty against any hospital or critical access hospital that knowingly makes a payment directly or indirectly to a physician (and any physician who receives such a payment) as an inducement to reduce or limit services[19] provided with respect to Medicare or Medicaid beneficiaries under the physician's direct care. Hospitals that make (and physicians who receive) such payments are liable for civil monetary penalties of up to $2,000 per patient covered by the payments. See id. There is no requirement that the prohibited payment be tied to a specific patient or to a reduction in medically necessary care. The CMP applies only to reductions or limitations of services provided to Medicare and Medicaid fee-for-

[18] In addition, nonprofit hospital arrangements raise issues of private inurement and private benefit under the Internal Revenue Service's income tax regulations in connection with section 501(c)(3) of the Internal Revenue Code. See Rev. Rul. 69-383, 1969-2 C.B. 113. We express no opinion on the application of the Internal Revenue Code to the Arrangement.

[19] We have interpreted services under the CMP to include items used or provided as part of a service.

service beneficiaries.[20] The CMP prohibits payments by hospitals to physicians as an inducement to a physician to reduce or limit services furnished to Medicare and Medicaid patients. A threshold inquiry is whether the Arrangement induces the Group's physicians to reduce or limit services. Given the specificity of the Arrangement, it is possible to review the opportunities for savings individually and evaluate their impact on patient care.

Having reviewed the Performance Fee components, we conclude that the Cost Savings Component implicates the CMP. With respect to the measures under the Arrangement regarding standardization of devices and supplies and limiting use of specific stents, contrast agents, and medical devices, the Arrangement might induce physicians to alter their current medical practice to reduce or limit services.[21] However, based on Requestor's certifications, we conclude that the Fixed Fee, Employee Satisfaction, Patient Satisfaction, and Quality Components contained in the Arrangement do not involve an inducement to reduce or limit services and, therefore, do not implicate the CMP. Notwithstanding that the CMP applies to the Cost Savings Component, the Arrangement has several features that, in combination, provide sufficient safeguards so that we would not seek sanctions against Requestor for the Arrangement under sections 1128A(b)(1)–(2) of the Act.

First, Requestor certified that the Arrangement has not adversely affected patient care.[22] Requestor also certified that it monitors both the performance of the Group under the

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[20] Physician incentive arrangements related to Medicare and Medicaid risk-based managed care contracts and Medicare Advantage plans are subject to regulation by the Secretary, pursuant to sections 1876(i)(8), 1903(m)(2)(A)(x), and 1852(j)(4) of the Act (respectively), in lieu of being subject to sections 1128A(b)(1)–(2). See OIG letter regarding hospital-physician incentive plans for Medicare and Medicaid beneficiaries enrolled in managed care plans (dated August 19, 1999), available at http://oig.hhs.gov/fraud/docs/alertsandbulletins/gsletter.htm. See also 42 C.F.R. § 417.479 (Medicare HMOs or competitive medical plans); 42 C.F.R. § 422.208 (Medicare Advantage plans); 42 C.F.R. § 438.6 (Medicaid risk plans).

[21] We recognize that the physicians' medical practice may have involved care that exceeded the requirements of medical necessity and thus would be reduced without posing a risk of harm to patients. However, liability under the CMP does not require that the payments be tied to a reduction in medically necessary care.

[22] An independent medical expert reviewed the Arrangement on behalf of OIG. The medical expert concluded that the quality and cost savings measures, as described in the advisory opinion request and supplemental submissions, should not have adversely affected patient care. For purposes of this opinion, however, we rely solely on Requestor's certifications, and nothing in this opinion should be construed as an

Arrangement and its implementation of the Cost Savings Component throughout the term of the Management Agreement to protect against inappropriate reductions or limitations in patient care or services. Requestor's Board of Directors, internal auditing staff, and certain hospital staff committees also monitor the Group's performance under the Arrangement. Additionally, Requestor uses an independent, external third-party utilization review firm to annually review data related to the components of the Performance Fee and the clinical appropriateness of the cardiac catheterization procedures performed at the Labs.

Second, the risk that the Arrangement will lead the Group's physicians to apply a specific cost savings measure, such as the use of a standardized or bare metal stent, in medically inappropriate circumstances is low. The parties structured the benchmarks within the Cost Savings Component of the Performance Fee to allow the Group's physicians flexibility to use the most cost-effective clinically appropriate items and supplies. Requestor certified that unique-sized stents or other types of drug-eluting stents remain available upon request by an interventional cardiologist, and that no physician is ever prohibited from requesting a particular device or supply required to address a patient's unique health needs. Thus, each of the Group's physicians has access to the device or supply he or she determines to be most clinically appropriate for each patient. The Arrangement is designed to produce savings through inherent clinical and fiscal value and not from restricting the availability of devices and supplies. The three-tiered benchmarks within the Cost Savings Component allow the Group to receive a portion of the Performance Fee based on the aggregated performance by the Group and not based on meeting a specific standard in the case of a particular patient if the standard is contraindicated with regard to that patient.

Third, the financial incentive tied to the Cost Savings Component is reasonably limited in duration and amount. The Performance Fee is subject to a maximum annual cap and the term of the Arrangement is limited to three years.

Fourth, receipt of any part of the Performance Fee under the Arrangement is conditioned upon the Group's physicians not taking any of the following actions: 1) stinting on care provided to Requestor's patients; 2) increasing referrals to Requestor; 3) cherry-picking healthy patients or those with desirable insurance for treatment in the Labs; or 4) accelerating patient discharges. While we believe such a contract provision alone would not sufficiently reduce the risk of harm to patients or Federal health care programs, in combination with other features of the Arrangement, it provides an additional safeguard on which we rely.

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endorsement or conclusion as to the medical propriety of the specific activities being undertaken as part of the Arrangement.

For all of these reasons, in an exercise of our discretion, we choose not to impose sanctions under the CMP as a result of the Arrangement.

B. The Anti-Kickback Statute

The anti-kickback statute makes it a criminal offense to knowingly and willfully offer, pay, solicit, or receive any remuneration to induce or reward referrals of items or services reimbursable by a Federal health care program. See section 1128B(b) of the Act. Where remuneration is paid purposefully to induce or reward referrals of items or services payable by a Federal health care program, the anti-kickback statute is violated. By its terms, the statute ascribes criminal liability to parties on both sides of an impermissible "kickback" transaction. For purposes of the anti-kickback statute, "remuneration" includes the transfer of anything of value, directly or indirectly, overtly or covertly, in cash or in kind.

The statute has been interpreted to cover any arrangement where one purpose of the remuneration was to obtain money for the referral of services or to induce further referrals. See, e.g., United States v. Borrasi, 639 F.3d 774 (7th Cir. 2011); United States v. McClatchey, 217 F.3d 823 (10th Cir. 2000); United States v. Davis, 132 F.3d 1092 (5th Cir. 1998); United States v. Kats, 871 F.2d 105 (9th Cir. 1989); United States v. Greber, 760 F.2d 68 (3d Cir.), cert. denied, 474 U.S. 988 (1985). Violation of the statute constitutes a felony punishable by a maximum fine of $25,000, imprisonment up to five years, or both. Conviction will also lead to automatic exclusion from Federal health care programs, including Medicare and Medicaid. Where a party commits an act described in section 1128B(b) of the Act, the OIG may initiate administrative proceedings to impose civil monetary penalties on such party under section 1128A(a)(7) of the Act. The OIG may also initiate administrative proceedings to exclude such party from the Federal health care programs under section 1128(b)(7) of the Act.

The Department of Health and Human Services has promulgated safe harbor regulations that define practices that are not subject to the anti-kickback statute because such practices would be unlikely to result in fraud or abuse. See 42 C.F.R. § 1001.952. The safe harbors set forth specific conditions that, if met, assure entities involved of not being prosecuted or sanctioned for the arrangement qualifying for the safe harbor. However, safe harbor protection is afforded only to those arrangements that precisely meet all of the conditions set forth in the safe harbor.

The safe harbor for personal services and management contracts, 42 C.F.R. § 1001.952(d), potentially applies to the Arrangement. In relevant part for purposes of this advisory opinion, the personal services safe harbor requires that the aggregate compensation paid for the services be set in advance and consistent with fair market value in arm's-length transactions. The Arrangement does not fit in the safe harbor because the aggregate payment to the Group is not set in advance. However, the absence

of safe harbor protection is not fatal. Instead, we evaluate the facts and circumstances specific to the Arrangement.

Like any compensation arrangement between a hospital and a physician who admits or refers patients to such hospital, we are concerned that the Arrangement could be used to disguise remuneration from Requestor to reward or induce referrals by the Group. Specifically, the Arrangement could encourage the physicians to admit Federal health care program patients to Requestor, because the physicians receive not only their Medicare Part B professional fee, but also may receive the Fixed Fee and the Performance Fee. While we believe the Arrangement could result in illegal remuneration if the requisite intent to induce referrals were present, for the following reasons we will not impose sanctions in the particular circumstances presented here and as qualified below.

First, Requestor certified that the compensation paid to the Group under the Management Agreement, which includes both the Fixed Fee and the Performance Fee, is fair market value for the services provided.[23] These services include overseeing Lab operations; providing strategic planning and medical direction services; developing Requestor's cardiology program; serving on medical staff committees; providing staff development and training; providing credentialing for Lab personnel; recommending Lab equipment, medical devices, and supplies; consulting with Requestor regarding information systems; providing assistance with financial and payor issues; and providing public relations services. The fact that the Group provides substantial services under the Management Agreement reduces the risk that compensation paid by Requestor is a payment for referrals, rather than for actual services rendered.

Second, the compensation paid to the Group does not vary with the number of patients treated. Thus, an increase in patient referrals to Requestor does not result in an increase in compensation paid to the Group under the Arrangement.[24]

Third, because Requestor operates the only cardiac catheterization laboratories within a fifty-mile radius, and because the Group does not provide cardiac catheterization services

[23] We are precluded by statute from opining on whether fair market value shall be or was paid for goods, services, or property. See Section 1128D(b)(3)(A) of the Act. If the fees are not fair market value, this opinion is without force and effect.

[24] We note that the Group distributes dividends *pro rata,* based on percentage ownership in the Group. We have no facts indicating that the Group allocates ownership interests or other compensation based on an individual physician owner's participation or performance under the Arrangement. We might have reached a different conclusion had this been the case.

at any location other than Requestor's Labs, it is unlikely that Requestor offered compensation to the Group under the Arrangement as an incentive for the Group's physicians to refer business to the Labs instead of to a competing cardiac catheterization lab.

Fourth, the specificity of the measures within the Arrangement helps ensure that its purpose is to improve quality, rather than reward referrals. The Arrangement specifically defines the Quality Component and bases the included measures on nationally recognized standards. The Arrangement sets out particular actions that generate the quality improvements on which the payments are based. The measures contained in the Quality and Cost Savings Components represent specific changes in cardiac catheterization laboratory procedures, which the Group's physicians are responsible for implementing. Additionally, the lowest, baseline achievement level for any measure reflects improvement over Requestor's *status quo* performance for that measure prior to the effective date of the Agreement.

Fifth, the Management Agreement is a written agreement with a three-year term, and thus is limited in duration.[25]

In light of these circumstances and safeguards, the Arrangement poses a low risk of fraud or abuse under the anti-kickback statute.[26]

III. CONCLUSION

Based on the facts certified in your request for an advisory opinion and supplemental submissions, we conclude that: (i) although the Arrangement could constitute an improper payment to induce the reduction or limitation of services pursuant to sections 1128A(b)(1) –(2) of the Act, the OIG will not impose sanctions on [name redacted] in connection with the Arrangement; and (ii) although the Arrangement could potentially

[25] We note that the Arrangement contains an automatic renewal provision, unless terminated; however, this advisory opinion applies only to the current three-year term. We express no opinion with respect to future extensions of the Arrangement. We would expect that quality improvement and cost saving measures under the Arrangement would be subject to adjustment over time, to avoid payment for improvements achieved in prior years and to provide incentives for additional improvements in the future. Continuing compensation for conduct that has come to represent the accepted standard of care could, depending on the circumstances, implicate the anti-kickback statute.

[26] We express no opinion with regard to any future changes in the Arrangement (particularly changes to the Quality or the Cost Savings Components) that diverge from those to which Requestor certified.

generate prohibited remuneration under the anti-kickback statute if the requisite intent to induce or reward referrals of Federal health care program business were present, the OIG will not impose administrative sanctions on [name redacted] under sections 1128(b)(7) or 1128A(a)(7) of the Act (as those sections relate to the commission of acts described in section 1128B(b) of the Act) in connection with the Arrangement. This opinion is limited to the Arrangement and, therefore, we express no opinion about any ancillary agreements or arrangements disclosed or referenced in your request for an advisory opinion or supplemental submissions.

IV. LIMITATIONS

- The limitations applicable to this opinion include the following:

- This advisory opinion is issued only to [name redacted], the requestor of this opinion. This advisory opinion has no application to, and cannot be relied upon by, any other individual or entity.

- This advisory opinion may not be introduced into evidence by a person or entity other than [name redacted] to prove that the person or entity did not violate the provisions of sections 1128, 1128A, or 1128B of the Act or any other law.

- This advisory opinion is applicable only to the statutory provisions specifically noted above. No opinion is expressed or implied herein with respect to the application of any other Federal, state, or local statute, rule, regulation, ordinance, or other law that may be applicable to the Arrangement, including, without limitation, the physician self-referral law, section 1877 of the Act (or that provision's application to the Medicaid program at section 1903(s) of the Act).

- This advisory opinion will not bind or obligate any agency other than the U.S. Department of Health and Human Services.

- This advisory opinion is limited in scope to the specific arrangement described in this letter and has no applicability to other arrangements, even those which appear similar in nature or scope.

- No opinion is expressed herein regarding the liability of any party under the False Claims Act or other legal authorities for any improper billing, claims submission, cost reporting, or related conduct.

This opinion is also subject to any additional limitations set forth at 42 C.F.R. Part 1008.

The OIG will not proceed against [name redacted] with respect to any action that is part of the Arrangement taken in good faith reliance upon this advisory opinion, as long as all of the material facts have been fully, completely, and accurately presented, and the Arrangement in practice comports with the information provided. The OIG reserves the right to reconsider the questions and issues raised in this advisory opinion and, where the public interest requires, to rescind, modify, or terminate this opinion. In the event that this advisory opinion is modified or terminated, the OIG will not proceed against [name redacted] with respect to any action that is part of the Arrangement taken in good faith reliance upon this advisory opinion, where all of the relevant facts were fully, completely, and accurately presented and where such action was promptly discontinued upon notification of the modification or termination of this advisory opinion. An advisory opinion may be rescinded only if the relevant and material facts have not been fully, completely, and accurately disclosed to the OIG.

Sincerely,

/Gregory E. Demske/

Gregory E. Demske
Chief Counsel to the Inspector General

[*We redact certain identifying information and certain potentially privileged, confidential, or proprietary information associated with the individual or entity, unless otherwise approved by the requester*.]

Date Issued: January 11, 2001

Date Posted: January 18, 2001

[Names and Addresses Redacted]

Re: OIG Advisory Opinion No. 01-1

Ladies & Gentlemen:

We are writing in response to your request for an advisory opinion concerning a proposed arrangement in which a hospital will share with a group of cardiac surgeons a percentage of the hospital's cost savings arising from the surgeons' implementation of a number of cost reduction measures in certain surgical procedures (the "Proposed Arrangement"). The cost savings will be measured based on the surgeons' use of specific supplies and medications during designated cardiac surgery procedures. You have inquired whether the Proposed Arrangement would constitute grounds for sanctions arising under (i) the civil monetary penalty for a hospital's payment to a physician to induce reductions or limitations of services to Medicare or Medicaid beneficiaries under the physician's direct care, section 1128A(b)(1)-(2) of the Social Security Act (the "Act"), or (ii) the anti-kickback statute, section 1128B(b) of the Act.

In issuing this opinion, we have relied solely on the facts and information presented to us. We have not undertaken an independent investigation of such information. This opinion is limited to the facts presented. If material facts have not been disclosed or have been misrepresented, this opinion is without force and effect.

Based on the information provided and the totality of the facts as described and certified in your request letter and supplemental submissions, we conclude that: (i) the Proposed Arrangement would constitute an improper payment to induce reduction or limitation of services pursuant to section 1128A(b)(1)-(2) of the Act, but that the Office of Inspector General ("OIG") will not impose sanctions on the requestors of this advisory opinion,

[names redacted] (the "Requestors"), in connection with the Proposed Arrangement; and (ii) the Proposed Arrangement would potentially generate prohibited remuneration under the anti-kickback statute, if the requisite intent to induce referrals were present, but that the OIG will not subject the Requestors to sanctions for violations of the anti-kickback statute under sections 1128(b)(7) or 1128A(a)(7) of the Act in connection with the Proposed Arrangement.

This opinion may not be relied on by any persons other than the Requestors and is further qualified as set out in Part IV below and in 42 C.F.R. Part 1008.

I. FACTUAL BACKGROUND

A. Parties

The Hospital. [Name redacted] (the "Hospital"), is an acute care, not-for-profit hospital in [City X], [State Y], that offers a broad range of inpatient and outpatient hospital services, including cardiac surgery services. The Hospital is a participating provider in the Medicare and Medicaid programs.

The Surgeon Group. [Name redacted] (the "Surgeon Group"), is a professional association composed exclusively of cardiac surgeons who are licensed in [State Y] and have active medical staff privileges at the Hospital. The cardiac surgeons refer patients to the Hospital for inpatient and outpatient hospital services. The Surgeon Group is the dominant group of cardiac surgeons that practices at the Hospital.[1] Surgeons in the Surgeon Group also practice at several other hospitals in the [City X] area.

The Program Administrator. The Hospital has engaged [name redacted] (the "Program Administrator") to administer the Proposed Arrangement. The Program Administrator will collect data and analyze and manage the Proposed Arrangement. The Hospital will pay the Program Administrator a monthly fixed fee certified by the Requestors to be fair market value in an arms-length transaction for services to be provided by the Program Administrator under the Proposed Arrangement. The fee will not be tied to cost savings or the Surgeon Group's compensation under the Proposed Arrangement.

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[1]Surgeons in the Surgeon Group perform 85% of the Hospital's cardiac surgery. Several cardiac surgeons who are not members of the Surgeon Group have active medical staff privileges at the Hospital. These cardiac surgeons will not participate in the Proposed Arrangement; however, the Hospital expects to include them in future cost savings sharing arrangements on terms and conditions substantially comparable to those under which it offers cost savings sharing to the Surgeon Group.

B. The Proposed Arrangement

Under the Proposed Arrangement, the Hospital will pay the Surgeon Group a share of the first year cost savings directly attributable to specific changes in the Surgeon Group's operating room practices. The Program Administrator conducted a study of the historic practices at the Hospital's cardiac surgery department and identified nineteen specific cost-savings opportunities. The results of the Program Administrator's study of the Surgeon Group and the specific cost-savings opportunities are summarized in a "Practice Patterns Report".[2] The Hospital and the Surgeon Group have reviewed the Practice Patterns Report for medical appropriateness and each has adopted its recommendations and conclusions.

In general, the Practice Patterns Report recommends that the Surgeon Group change its current operating room practices to curb the inappropriate use or waste of medical supplies. The nineteen specific recommendations can be roughly grouped into three categories. The first category consists of fourteen recommendations that involve opening packaged items only as needed during a procedure. Most of these "open as needed" items are surgical tray or comparable supplies. These items will be readily available, albeit unopened, in the operating room. One "open as needed" recommendation involves not opening disposable components of the cell saver unit until a patient experiences excessive bleeding. The Requestors have certified that the resulting delay in cell saver readiness should not exceed two to five minutes and will not adversely affect patient care. The second category, involving four recommendations, consists of the substitution, in whole or in part, of less costly items for the items currently being used by the surgeons. The final category consists of a recommendation to limit use of Aprotinin – a medication currently given to many surgical patients pre-operatively to prevent hemorrhaging – to patients that are at higher risk of perioperative hemorrhage as indicated by objective clinical standards.

The Proposed Arrangement contains several safeguards intended to protect against inappropriate reductions in services. With respect to the cell saver and the substitution recommendations, the Proposed Arrangement would utilize objective historical and clinical measures reasonably related to the practices and the patient population at the Hospital to establish a "floor" below which no savings would accrue to the Surgeon Group. For example, the cell saver is currently used in approximately [A]% of the cardiac procedures specified under the Proposed Arrangement. Accordingly, the Surgeon Group will receive no share of any savings resulting from any reductions in cell saver use

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[2]The Practice Patterns Report for the Surgeon Group, dated April 4, 2000, is attached to this advisory opinion as Appendix A.

for cases below the [A]% floor. Similarly, for each of the proposed substitution recommendations, the Program Administrator has identified historic patterns of use at the Hospital or at hospitals with comparable practices and patient populations and has established thresholds below which no cost savings will be credited. For example, the Practice Patterns Report indicates that certain less expensive forms of sutures could be used in [B]% of the cases without having an adverse impact on patient care.[3] Accordingly, any savings from using less expensive sutures in more than [B]% of the cases will not be credited to the Surgeon Group.

With respect to Aprotinin, the Proposed Arrangement uses specific, objective, generally-accepted clinical indicators reasonably related to the practices of the Hospital and its patient population to determine medical appropriateness.[4] Currently, approximately [C]% of patients to whom Aprotinin is administered by the Surgeon Group at the Hospital meet these objective clinical indicators. Under the Proposed Arrangement, savings from reduced use of Aprotinin will not be credited to the Surgeon Group if the savings result from utilization of Aprotinin in less than [C]% of cases or if the savings result from failure to use Aprotinin in a case that meets the clinical indicators. All surgical cases – including cases in which Aprotinin is not administered – will be reviewed by the Program Administrator to determine if the surgeons followed the objective clinical indicators for determining whether Aprotinin was used appropriately.

According to the Program Administrator, if implemented in accordance with the Practice Patterns Report's specifications, the nineteen recommendations would present substantial cost savings opportunities for the Hospital without adversely impacting the quality of patient care. Seventy-five percent of the potential cost savings would come from the proposed reduction in routine use of Aprotinin and another ten percent from the proposed delay in setting up the cell saver.

The Hospital will pay the Surgeon Group 50% of the cost savings achieved by implementing the nineteen recommendations in the Practice Patterns Report for a period of one year. At the end of the year, cost savings will be calculated separately for each of the nineteen recommendations; this will preclude shifting of cost savings and ensure that savings generated by utilization below the set targets will not be credited to the Surgeon

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[3]We note that the Practice Patterns Report identifies with specificity the kinds of sutures at issue.

[4]The objective clinical indicators used in the Proposed Arrangement to determine when Aprotinin is administered appropriately are cited in medical literature. Lemmer et al., ATS 62: 1659-68 (1996).

Group. This payment will constitute the entire compensation paid to the Surgeon Group for services performed under the contract memorializing the Proposed Arrangement between the Surgeon Group and the Hospital. The payment to the Surgeon Group will be calculated by subtracting the actual costs incurred for the items specified in the nineteen recommendations when used by surgeons in the Surgeon Group during the specified surgical procedures (the "current year costs"[5]) from the historic costs for the same items when used during comparable surgical procedures in the base year (the "base year costs"[6]). The current year costs will be adjusted to account for any inappropriate reductions in use of items below the targets set in the Practice Patterns Report. The Surgeon Group will be paid 50% of the difference between the adjusted current year costs and base year costs, if any.

The Hospital will make an aggregate payment to the Surgeon Group, which distributes its profits to each of its members on a per capita basis. Payments to the Surgeon Group will also be subject to the following limitations:

- If the volume of procedures payable by a Federal health care program in the current year exceeds the volume of like procedures payable by a Federal health care program performed in the base year, there will be no sharing of cost savings for the additional procedures.

- To minimize the surgeons' financial incentive to steer more costly patients to other hospitals, the case severity, ages, and payors of the patient population treated under the Proposed Arrangement will be monitored by a committee composed of representatives of the Requestors, using generally-accepted standards. If there are significant changes from historical measures, the surgeon at issue will be terminated from participation in the Proposed Arrangement.

- The aggregate payment to the Surgeon Group will not exceed 50% of the

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[5]The current year will be the twelve month term of the contract for which the Surgeon Group will be compensated under the Proposed Arrangement.

[6]The "base year" will be the twelve months preceding the effective date of the contract. For purposes of this opinion, the Proposed Arrangement is limited to the one year term of the contract; accordingly, this opinion is without force and effect with respect to any future renewal or extension of the Proposed Arrangement. Notwithstanding, we note that any renewal or extension of the Proposed Arrangement should incorporate updated base year costs.

projected cost savings identified in the Practice Patterns Report.

The Requestors have certified that this payment methodology will generate payments to the Surgeon Group that will be consistent with fair market value for services rendered to the Hospital in arms-length transactions.

The Hospital and the Surgeon Group will document the activities and the payment methodology under the Proposed Arrangement and will make the documentation available to the Secretary of the U.S. Department of Health and Human Services (the "Department"), upon request. In addition, the Hospital and the Surgeon Group will disclose the Proposed Arrangement to the patient, including the fact that the Surgeon Group's compensation is based on a percentage of the Hospital's cost savings. The disclosure will be made to the patient before the patient is admitted to the Hospital for a procedure covered by the Proposed Arrangement; if pre-admission disclosure is impracticable (e.g., the patient is admitted for an unscheduled procedure or the need for the procedure is determined after admission), the disclosure will be made before the patient consents to the surgery. The disclosures will be in writing, and patients will have an opportunity, if desired, to review details of the Proposed Arrangement, including the specific cost savings measures applicable to the patient's surgery.

II. LEGAL ANALYSIS

Arrangements like the Proposed Arrangement are designed to align incentives by offering physicians a portion of a hospital's cost savings in exchange for implementing cost saving strategies. Under the current reimbursement system, the burden of these costs falls on hospitals, not physicians. Payments based on cost savings to physicians may be intended to motivate them to reduce hospital costs associated with procedures performed by physicians at the hospitals.

Properly structured, cost sharing arrangements can serve legitimate business and medical purposes. Specifically, properly structured arrangements may increase efficiency and reduce waste, thereby potentially increasing a hospital's profitability. However, such arrangements can potentially influence physician judgment to the detriment of patient care. Our concerns include, but are not limited to, the following: (i) stinting on patient care; (ii) "cherry picking" healthy patients and steering sicker (and more costly) patients to hospitals that do not offer such arrangements; (iii) payments in exchange for patient referrals; and (iv) unfair competition (a "race to the bottom") among hospitals offering cost sharing programs to foster physician loyalty and to attract more referrals.

Hospital cost savings programs in general, and the Proposed Arrangement in particular, may implicate at least three legal authorities: (i) the civil monetary penalty for reductions

or limitations of direct patient care services provided to Federal health care program beneficiaries, section 1128A(b)(1)-(2) of the Act; (ii) the anti-kickback statute, section 1128B(b) of the Act; and (iii) the physician self-referral law, section 1877 of the Act.[7] We address the first two of these authorities; section 1877 of the Act falls outside the scope of the OIG's advisory opinion authority. We express no opinion on the application of section 1877 to the Proposed Arrangement.

A. The Civil Monetary Penalty, Section 1128A(b)(1)-(2) of the Act

Section 1128A(b)(1)-(2) of the Act establishes a civil monetary penalty ("CMP") against any hospital or critical access hospital that knowingly makes a payment directly or indirectly to a physician (and any physician that receives such a payment) as an inducement to reduce or limit items or services to Medicare or Medicaid beneficiaries under the physician's direct care. Hospitals that make (and physicians that receive) such payments are liable for CMPs of up to $2,000 per patient covered by the payments (section 1128A(b)(1) & (2) of the Act). There is no requirement that the prohibited payment be tied to a specific patient or to a reduction in medically necessary care. The CMP applies only to reductions or limitations of items or services provided to Medicare and Medicaid fee-for-service beneficiaries.[8]

The CMP prohibits payments by hospitals to physicians that may induce physicians to reduce or limit items or services furnished to their Medicare and Medicaid patients. A threshold inquiry is whether the Proposed Arrangement will induce physicians to reduce or limit items or services. Given the specificity of the Proposed Arrangement, it is possible to review the proposed opportunities for savings individually and evaluate their

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[7]In addition, non-profit hospital arrangements raise issues of private inurement and private benefit under the Internal Revenue Service's income tax regulations in connection with section 501(c)(3) of the Internal Revenue Code. See Rev. Rul. 69-383, 1969-2 C.B. 113.

[8]Physician incentive arrangements related to Medicare risk-based managed care contracts, similar Medicaid contracts, and Medicare + Choice plans are subject to regulation by the Secretary pursuant to sections 1876(i)(8), 1903(m)(2)(A)(x), and 1852(j)(4) of the Act (respectively), in lieu of being subject to sections 1128A(b)(1) and (2). See OIG letter regarding hospital-physician incentive plans for Medicare and Medicaid beneficiaries enrolled in managed care plans (dated August 19, 1999), available at http://oig.hhs.gov/frdalrt/gsletter.htm; see also 42 C.F.R. § 417.479(i); 61 Fed. Reg. 13430, 13439 (Mar. 27, 1996); 42 C.F.R. § 434.70 (comparable regulations for physician incentive plans associated with Medicaid managed care organizations).

potential impact on patient care.

Having reviewed the nineteen individual recommendations, we conclude that, except for the unopened surgical tray items (discussed in more detail below), the recommendations implicate the CMP. Simply put, with respect to the recommendations regarding the disposable cell saver components, Aprotinin, and the substitution of less costly items, the Proposed Arrangement constitutes an inducement to reduce or limit the current medical practice at the Hospital. We recognize that the current medical practice may involve care that exceeds the requirements of medical necessity. However, whether the current medical practice reflects necessity or prudence is irrelevant for purposes of the CMP.

With respect to the recommendations regarding "open as needed" surgical tray items, we reach a different conclusion. To the extent that the sole delay in providing items or services is the insubstantial time it takes to open a package of supplies readily available in the operating room, we believe there will be no perceptible reduction or limitation in the provision of items or services to patients sufficient to trigger the CMP. However, this conclusion does not apply to the disposable cell saver components. Because the components must be attached to the machine and the machine must be started up, there will be an additional delay in the cell saver's availability beyond merely opening the disposable components. Therefore, there is a greater potential for harm. Accordingly, we conclude that the cell saver incentive is subject to the statutory proscription of the CMP.

In sum, while the recommendations for the "open as needed" surgical tray items do not run afoul of the CMP, we find that the CMP would apply to the remaining recommendations involving the cell saver components, Aprotinin, and the various substitutions. Notwithstanding, the Proposed Arrangement has several features that, in combination, provide sufficient safeguards so that we would not seek sanctions against the Requestors under section 1128A(b)(1) and (2) of the Act.

First, the specific cost-saving actions and resulting savings are clearly and separately identified. The transparency of the Proposed Arrangement will allow for public scrutiny and individual physician accountability for any adverse effects of the Proposed Arrangement, including any difference in treatment among patients based on non-clinical indicators. The transparency of the incentives for specific actions and specific procedures will also facilitate accountability through the medical-legal professional liability system.

Second, the Requestors have proffered credible medical support for the position that implementation of the recommendations, including the reduction in routine use of Aprotinin, will not adversely affect patient care. The Proposed Arrangement will be periodically reviewed to confirm that the Proposed Arrangement is not having an adverse

impact on clinical care.[9]

Third, the payments under the Proposed Arrangement are based on all surgeries regardless of the patients' insurance coverage, subject to the cap on payment for Federal health care program procedures. Moreover, the surgical procedures to which the Proposed Arrangement applies are not disproportionately performed on Federal health care program beneficiaries. Additionally, the cost savings are calculated on the Hospital's actual out-of-pocket acquisition costs, not an accounting convention.

Fourth, the Proposed Arrangement protects against inappropriate reductions in services by utilizing objective historical and clinical measures to establish baseline thresholds below which no savings accrue to the Surgeon Group. The Requestors have certified that these baseline measures are reasonably related to the Hospital's or comparable hospitals' practices and patient populations. These safeguards are action-specific and not simply based on isolated patient outcome data unrelated to the specific changes in operating room practices.

Fifth, the Hospital and the Surgeon Group will provide written disclosures of their involvement in the Proposed Arrangement to patients whose care may be affected by the Proposed Arrangement and will provide patients an opportunity to review the cost savings recommendations prior to admission to the Hospital (or, where pre-admission consent is impracticable, prior to consenting to surgery). While we do not believe that, standing alone, such disclosures offer sufficient protection from program or patient abuse, effective and meaningful disclosure offers some protection against possible abuses of patient trust.[10]

Sixth, the financial incentives under the Proposed Arrangement are reasonably limited in

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[9]We have had the Proposed Arrangement reviewed by an independent medical expert, as well as a government medical expert. Both have concluded that the proposed cost savings measures, as described in the advisory opinion request and supplemental submissions, should not adversely affect patient care. For purposes of this opinion, however, we rely solely on the Requestors' certifications and nothing in this advisory opinion should be construed as an endorsement or conclusion as to the medical propriety of the specific activities being undertaken as part of the Proposed Arrangement.

[10]Ordinarily, we would expect patient disclosures to be coupled with patient satisfaction surveys that closely monitor patient perceptions of their care. However, in the context of the Proposed Arrangement, which focuses on items and medications used in operating rooms, we believe that patient satisfaction surveys would not be effective.

duration and amount.

Seventh, because the Surgeon Group's profits are distributed to its members on a per capita basis, any incentive for an individual surgeon to generate disproportionate cost savings is mitigated.

Our decision not to impose sanctions on the Requestors in connection with the Proposed Arrangement is an exercise of our discretion and is consistent with our Special Advisory Bulletin on "Gainsharing Arrangements and CMPs for Hospital Payments to Physicians to Reduce or Limit Services to Beneficiaries" (July 1999) (the "Special Advisory Bulletin"). We reiterate that the CMP applies to any payment by a hospital to a physician that is intended to induce the reduction or limitation of items or services to Medicare or Medicaid patients under the physician's direct clinical care. The Proposed Arrangement is markedly different from many "gainsharing" plans, particularly those that purport to pay physicians a percentage of generalized cost savings not tied to specific, identifiable cost-lowering activities. Importantly, the Proposed Arrangement sets out the specific actions to be taken and ties the remuneration to the actual, verifiable cost savings attributable to those actions. This transparency allows an assessment of the likely effect of the Proposed Arrangement on quality of care and ensures that the identified actions will be the cause of the savings.

By contrast, many gainsharing plans contain features that heighten the risk that payments will lead to inappropriate reductions or limitations of services. These features include, but are not limited to, the following:

- There is no demonstrable direct connection between individual actions and any reduction in the hospital's out-of-pocket costs (and any corresponding "gainsharing" payment).

- The individual actions that would give rise to the savings are not identified with specificity.

- There are insufficient safeguards against the risk that the other, unidentified actions, such as premature hospital discharges, might actually account for any "savings."

- The quality of care indicators are of questionable validity and statistical significance.

- There is no independent verification of cost savings, quality of care indicators, or other essential aspects of the arrangement.

Simply put, many "gainsharing" plans present substantial risks for both patient and program abuse – risks that are not present in the Proposed Arrangement. Given the limited duration and scope of the Proposed Arrangement, the safeguards provide sufficient protections against patient and program abuse. Other arrangements, including those that are longer in duration or more expansive in scope than the Proposed Arrangement, are likely to require additional or different safeguards.

B. The Anti-Kickback Statute

The anti-kickback statute makes it a criminal offense knowingly and willfully to offer, pay, solicit, or receive any remuneration to induce referrals of items or services reimbursable by any Federal health care program. See section 1128B(b) of the Act. Specifically, the statute provides that:

> Whoever knowingly and willfully offers or pays [or solicits or receives] any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person -- to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program, shall be guilty of a felony.

Id. Thus, where remuneration is paid purposefully to induce referrals of items or services for which payment may be made by a Federal health care program, the anti-kickback statute is violated. By its terms, the statute ascribes criminal liability to parties on both sides of an impermissible "kickback" transaction. For purposes of the anti-kickback statute, "remuneration" includes the transfer of anything of value, in cash or in-kind, directly or indirectly, covertly or overtly.

The statute has been interpreted to cover any arrangement where one purpose of the remuneration was to obtain money for the referral of services or to induce further referrals. United States v. Kats, 871 F.2d 105 (9th Cir. 1989); United States v. Greber, 760 F.2d 68 (3d Cir.), cert. denied, 474 U.S. 988 (1985). Violation of the statute constitutes a felony punishable by a maximum fine of $25,000, imprisonment up to five years, or both. Conviction will also lead to automatic exclusion from Federal health care programs, including Medicare and Medicaid. The OIG may also initiate administrative proceedings to exclude persons from Federal and State health care programs or to impose

civil monetary penalties for fraud, kickbacks, and other prohibited activities under sections 1128(b)(7) and 1128A(a)(7) of the Act.[11]

The Department of Health and Human Services has promulgated safe harbor regulations that define practices that are not subject to the anti-kickback statute because such practices would be unlikely to result in fraud or abuse. See 42 C.F.R. § 1001.952. The safe harbors set forth specific conditions that, if met, assure entities involved of not being prosecuted or sanctioned for the arrangement qualifying for the safe harbor. However, safe harbor protection is afforded only to those arrangements that precisely meet all of the conditions set forth in the safe harbor. The regulatory safe harbor potentially applicable to the Proposed Arrangement is the personal services and management contracts safe harbor, 42 C.F.R. § 1001.952(d). In relevant part for purposes of this advisory opinion, the personal services safe harbor requires that the aggregate compensation paid for the services be set in advance and consistent with fair market value in an arms-length transactions, 42 C.F.R. § 1001.952(d)(5). The Proposed Arrangement would not fit in the safe harbor because the Surgeon Group will be paid on a percentage basis, and thus the compensation would not be set in advance. However, the absence of safe harbor protection is not fatal. Instead, the Proposed Arrangement must be subject to case-by-case evaluation.

Like any compensation arrangement between a hospital and a physician who admits or refers patients to such hospital, we are concerned that the Proposed Arrangement could be used to disguise remuneration from the Hospital to reward or induce referrals by the Surgeon Group. Specifically, the Proposed Arrangement could encourage the surgeons to admit Federal health care program patients to the Hospital, since the surgeons would receive not only their Medicare Part B professional fee, but also, indirectly, a share of the Hospital's payment, depending on cost savings. In other words, the more procedures a surgeon performs at the Hospital, the more money he or she is likely to receive under the Proposed Arrangement.

While we believe the Proposed Arrangement could result in illegal remuneration if the requisite intent to induce referrals were present, we would not impose sanctions in the particular circumstances presented here. First, the circumstances and safeguards of the Proposed Arrangement reduce the likelihood that the arrangement will be used to attract referring physicians or to increase referrals from existing physicians. Specifically, participation in the Proposed Arrangement will be limited to surgeons already on the

[11]Because both the criminal and administrative sanctions related to the anti-kickback implications of the Arrangement are based on violations of the anti-kickback statute, the analysis for purposes of this advisory opinion is the same under both.

medical staff, thus limiting the Proposed Arrangement's effectiveness in attracting other surgeons. Only surgeons in the Surgeon Group will participate; however, based on the Requestors' certifications, we expect that if the Proposed Arrangement is renewed or continued beyond the one year term, the Hospital and the Program Administrator will offer a substantially comparable cost savings program to other cardiac surgeons on the medical staff. In addition, the potential savings derived from procedures for Federal health care program beneficiaries will be capped based on the prior year's admissions of Federal health care program beneficiaries. Finally, the contract term will be limited to one year, reducing any incentive to switch facilities, and admissions will be monitored for changes in severity, age, or payer. Thus, while the incentive to refer will not necessarily be eliminated, it will be substantially reduced.

Second, the structure of the Proposed Arrangement eliminates the risk that the Proposed Arrangement will be used to reward cardiologists or other physicians who refer patients to the Surgeon Group or its surgeons. The Surgeon Group is the sole participant in the Proposed Arrangement and is composed entirely of cardiac surgeons; no cardiologists or other physicians are members of the Surgeon Group or share in its profit distributions. Within the Surgeon Group, profits are distributed to its members on a per capita basis, mitigating any incentive for an individual surgeon to generate disproportionate cost savings.

Third, the Proposed Arrangement sets out with specificity the particular actions that will generate the cost savings on which the payments are based. While many of the recommendations in the Practice Patterns Report are simple common sense, they do represent a change in operating room practice for which the surgeon is responsible and will have liability exposure. While most of the recommendations would appear to present minimal risk, the preparation of the cell saver and the administration of Aprotinin both carry some increased liability risk for the physicians. It is not unreasonable for the surgeon to receive compensation for the increased risk from the proposed change in practice. Moreover, the payments will represent a portion of one year's worth of cost savings and will be limited in amount (i.e., the aggregate cap), duration (i.e., the limited contract term), and scope (i.e., the total savings that can be achieved from the implementation of any one recommendation are limited by appropriate utilization levels). While we are precluded from opining on whether a payment is fair market value,[12] the payments under the Proposed Arrangement do not appear unreasonable, given, among other things, the nature of the nineteen recommended actions, the specificity of the payment formula, and the cap on total remuneration to the Surgeon Group. We caution

[12]We are precluded by statute from opining on whether fair market value shall be or was paid for goods, services, or property. See 42 U.S.C. § 1320a-7d(b)(3)(A).

that payments of 50% of cost savings in other arrangements, including multi-year arrangements or arrangements with generalized cost savings formulae, could well lead to a different result.

In light of these circumstances and safeguards, the Proposed Arrangement poses a low risk of fraud or abuse under the anti-kickback statute.

III. CONCLUSION

Notwithstanding the foregoing, we reiterate our concerns regarding many arrangements between hospitals and physicians to share cost savings. Improperly designed or implemented arrangements risk adversely affecting patient care and could be vehicles to disguise payments for referrals. For example, an arrangement that cannot be adequately and accurately measured for quality of care would pose a high risk of fraud or abuse, as would one that rewards physicians based on overall cost savings without accountability for specific cost reduction measures. Moreover, arrangements structured so as to pose a heightened potential for patient steering and unfair competition would be considered suspect. In short, this opinion is predicated on the specific arrangement posed by the Requestors and is limited to that specific arrangement. Other apparently similar arrangements could raise different concerns and lead to a different result.

Based on the information provided, we conclude: (i) the Proposed Arrangement would constitute an improper payment to induce reduction or limitation of services pursuant to section 1128A(b)(1)-(2) of the Act, but that the OIG will not impose sanctions under section 1128A(b)(1)-(2) on the Requestors in connection with the Proposed Arrangement; and (ii) the Proposed Arrangement would potentially generate prohibited remuneration under the anti-kickback statute, if the requisite intent to induce referrals were present, but that, based on the totality of the facts present in the Proposed Arrangement as described and certified in the request letter and supplemental submissions, the OIG will not subject the Requestors to sanctions for violations of the anti-kickback statute under sections 1128(b)(7) or 1128A(a)(7) of the Act.

IV. LIMITATIONS

The limitations applicable to this opinion include the following:

- This advisory opinion is issued only to [names redacted], the requestors of this opinion. This advisory opinion has no application to, and cannot be relied upon by, any other individual or entity.

- This advisory opinion may not be introduced into evidence in any matter involving an entity or individual that is not a requestor to this opinion.

- This advisory opinion is applicable only to the statutory provisions specifically noted above in the first paragraph of this opinion. No opinion is herein expressed or implied with respect to the application of any other Federal, state, or local statute, rule, regulation, ordinance, or other law that may be applicable to the Proposed Arrangement.

- This advisory opinion will not bind or obligate any agency other than the U.S. Department of Health and Human Services.

- This advisory opinion is limited in scope to the specific arrangement described in this letter and has no applicability to other arrangements, even those that appear similar in nature or scope.

- No opinion is expressed herein regarding the liability of any party under the False Claims Act or other legal authorities for any improper billing, claims submission, cost reporting, or related conduct.

This opinion is also subject to any additional limitations set forth at 42 C.F.R. Part 1008.

The OIG will not proceed against the Requestors with respect to any action that is part of the Proposed Arrangement taken in good faith reliance upon this advisory opinion as long as all of the material facts have been fully, completely, and accurately presented, and the Proposed Arrangement in practice comports with the information provided. The OIG reserves the right to reconsider the questions and issues raised in this advisory opinion and, where the public interest requires, rescind, modify, or terminate this opinion. In the event that this advisory opinion is modified or terminated, the OIG will not proceed

against the Requestors with respect to any action taken in good faith reliance upon this advisory opinion, where all of the relevant facts were fully, completely, and accurately presented, and where such action was promptly discontinued upon notification of the modification or termination of this advisory opinion. An advisory opinion may be rescinded only if the relevant and material facts have not been fully, completely, and accurately disclosed to the OIG.

Sincerely,

/s/

D. McCarty Thornton
Chief Counsel to the Inspector General

[Appendix A redacted]

[*We redact certain identifying information and certain potentially privileged, confidential, or proprietary information associated with the individual or entity, unless otherwise approved by the requestors.*]

Issued: January 28, 2005

Posted: February 4, 2005

[names and addresses redacted]

Re: **OIG Advisory Opinion No. 05-01**

Ladies and Gentlemen:

We are writing in response to your request for an advisory opinion concerning a proposed arrangement in which a hospital will share with a group of cardiac surgeons a percentage of the hospital's cost savings arising from the surgeons' implementation of a number of cost reduction measures in certain surgical procedures (the "Proposed Arrangement"). The cost savings will be measured based on the surgeons' use of specific supplies during designated cardiac surgery procedures. You have inquired whether the Proposed Arrangement would constitute grounds for sanctions arising under: (i) the civil monetary penalty for a hospital's payment to a physician to induce reductions or limitations of services to Medicare or Medicaid beneficiaries under the physician's direct care, sections 1128A(b)(1)-(2) of the Social Security Act (the "Act"); or (ii) the exclusion authority at section 1128(b)(7) of the Act or the civil monetary penalty provision at section 1128A(a)(7) of the Act, as those sections relate to the commission of acts described in section 1128B(b) of the Act, the anti-kickback statute.

You have certified that all of the information provided in your request, including all supplementary letters, is true and correct and constitutes a complete description of the relevant facts and agreements among the parties.

In issuing this opinion, we have relied solely on the facts and information presented to us. We have not undertaken an independent investigation of such information. This opinion is limited to the facts presented. If material facts have not been disclosed or have been misrepresented, this opinion is without force and effect.

Based on the information provided and the totality of the facts as described and certified in your request for an advisory opinion and supplemental submissions, we conclude that: (i) the Proposed Arrangement would constitute an improper payment to induce reduction or limitation of services pursuant to sections 1128A(b)(1)-(2) of the Act, but that the Office of Inspector General ("OIG") would not impose sanctions on the requestors of this advisory opinion, [names redacted] (the "Requestors"), in connection with the Proposed Arrangement; and (ii) the Proposed Arrangement would potentially generate prohibited remuneration under the anti-kickback statute, if the requisite intent to induce or reward referrals of Federal health care program business were present, but that the OIG would not impose administrative sanctions on the Requestors under sections 1128(b)(7) or 1128A(a)(7) of the Act (as those sections relate to the commission of acts described in section 1128B(b) of the Act) in connection with the Proposed Arrangement.

This opinion may not be relied on by any persons other than the Requestors and is further qualified as set out in Part IV below and in 42 C.F.R. Part 1008.

I. FACTUAL BACKGROUND

A. Parties

The Hospital. [Name redacted] (the "Hospital") is an acute care hospital in [city and state redacted], that offers a broad range of inpatient and outpatient hospital services, including cardiac surgery services. The Hospital is a participating provider in the Medicare and Medicaid programs.

The Surgeon Group. [Name redacted] (the "Surgeon Group") is a professional association composed exclusively of cardiac surgeons who are licensed in [state redacted] and have active medical staff privileges at the Hospital. The cardiac surgeons refer patients to the Hospital for inpatient and outpatient hospital services. The Surgeon Group is the only group of cardiac surgeons that practices at the Hospital.[1]

The Program Administrator. The Hospital has engaged [name redacted] (the "Program Administrator") to administer the Proposed Arrangement. The Program Administrator will collect data and analyze and manage the Proposed Arrangement.[2] The Hospital will pay the Program Administrator a monthly fixed fee certified by the Requestors to be fair market value in an arm's-length transaction for services to be provided by the Program Administrator under the Proposed Arrangement. The fee will not be tied in any way to cost savings or the Surgeon Group's compensation under the Proposed Arrangement.

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[1]Surgeons in the Surgeon Group also practice at two other hospitals in the region.

[2]The Program Administrator has developed software products that measure cost, quality, and utilization on a national basis. The products are certified by both the American College of Cardiology and the Society of Thoracic Surgery.

B. The Proposed Arrangement

Under the Proposed Arrangement, the Hospital will pay the Surgeon Group a share of the first year cost savings directly attributable to specific changes in the Surgeon Group's operating room practices. The Program Administrator conducted a study of the historic practices at the Hospital's cardiac surgery department and identified twenty-four specific cost-savings opportunities. The results of the Program Administrator's study of the Surgeon Group and the specific cost-savings opportunities are summarized in a "Practice Patterns Report."[3] The Hospital and the Surgeon Group have reviewed the Practice Patterns Report for medical appropriateness and each has adopted its recommendations and conclusions.

In general, the Practice Patterns Report recommends that the Surgeon Group change its current operating room practices to curb the inappropriate use or waste of medical supplies. The Practice Patterns Report identifies twenty-four specific recommendations that can be roughly grouped into the following four categories.

The first category consists of eleven recommendations that involve opening packaged items only as needed during a procedure. Most of these "open as needed" items are surgical tray or comparable supplies. These items will be readily available, albeit unopened, in the operating room. One "open as needed" recommendation involves not opening disposable components of the cell saver unit until a patient experiences excessive bleeding. The Requestors have certified that the resulting delay in cell saver readiness should not exceed two to five minutes and will not adversely affect patient care.

The second category is similar and involves performing blood cross-matching only as needed. The Requestors have certified that all patients would be typed and screened prior to the procedure, with a cross-match being performed only when a patient requires a transfusion. The Hospital does not outsource its blood supply. The Requestors have certified that the resulting delay in blood readiness should be minimal when a cross match is necessary and that the delay will not adversely affect patient care.

The third category, involving seven recommendations, consists of the substitution, in whole or in part, of less costly items for the items currently being used by the surgeons.

The final category, involving five recommendations, consists of product standardization of certain cardiac devices where medically appropriate. For this category, the Surgeon Group would be required to work in conjunction with the Hospital to evaluate and

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[3]The Practice Patterns Report for the Surgeon Group, dated October 2004, is attached to this advisory opinion as Appendix A. This opinion is based on the specific cost savings recommendations and associated facts (e.g., specific floors set for each recommendation) set forth in the Practice Patterns Report as appropriate for the Requestors. Similar cost savings recommendations involving different facts could produce a different result.

clinically review vendors and products.[4] The Surgeon Group would agree to use the selected products where medically appropriate, which may require additional training or changes in clinical practice.

The Proposed Arrangement contains several safeguards intended to protect against inappropriate reductions in services. With respect to the cell saver, blood cross-matching, and the substitution recommendations, the Proposed Arrangement would utilize objective historical and clinical measures reasonably related to the practices and the patient population at the Hospital to establish a "floor" beyond which no savings would accrue to the Surgeon Group. For example, the cell saver is currently set-up for 100% of the cases, but is only utilized in approximately 30% of the cardiac procedures specified under the Proposed Arrangement. Accordingly, the Surgeon Group will receive no share of any savings resulting from any reductions in cell saver use for cases beyond the 30% floor. Similarly, blood cross-matching is currently performed for 100% of the cases, with less than 30% of the cases actually resulting in a transfusion. Thus, the Surgeon Group will receive no share of any savings resulting from the reduction of blood cross-matching beyond the 30% floor. For each of the proposed substitution recommendations, the Program Administrator has identified historic patterns of use at the Hospital or at hospitals with comparable practices and patient populations and has established thresholds beyond which no cost savings will be credited. For example, the Practice Patterns Report indicates that certain less expensive catheters could be used in 90% of the cases without having an adverse impact on patient care.[5] Accordingly, any savings from using less expensive catheters in more than 90% of the cases will not be credited to the Surgeon Group.

Importantly, with respect to the product standardization recommendations, the Requestors have certified that the individual surgeons will make a patient-by-patient determination of the most appropriate cardiac device and the availability of the full range of cardiac devices will not be compromised by the product standardization. The Requestors have further certified that individual physicians will still have available the same selection of devices after implementation of the Proposed Arrangement as before and that the economies gained through the Proposed Arrangement will result from inherent clinical and fiscal value and not from restricting the availability of devices.

According to the Program Administrator, if implemented in accordance with the Practice Patterns Report's specifications, the twenty-four recommendations would present substantial cost savings opportunities for the Hospital without adversely impacting the quality of patient care.

The Hospital will pay the Surgeon Group 50% of the cost savings achieved by

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[4]We note that the Practice Patterns Report identifies with specificity the vendors and products at issue.

[5]We note that the Practice Patterns Report identifies with specificity the catheters at issue.

implementing the twenty-four recommendations in the Practice Patterns Report for a period of one year. At the end of the year, cost savings will be calculated separately for each of the twenty-four recommendations; this will preclude shifting of cost savings and ensure that savings generated by utilization beyond the set targets, as applicable, will not be credited to the Surgeon Group. This payment will constitute the entire compensation paid to the Surgeon Group for services performed under the contract memorializing the Proposed Arrangement between the Surgeon Group and the Hospital. For purposes of calculating the payment to the Surgeon Group, the cost savings will be calculated by subtracting the actual costs incurred for the items specified in the twenty-four recommendations when used by surgeons in the Surgeon Group during the specified surgical procedures (the "current year costs"[6]) from the historic costs for the same items when used during comparable surgical procedures in the base year (the "base year costs"[7]). The current year costs will be adjusted to account for any inappropriate reductions in use of items beyond the targets set in the Practice Patterns Report. The payment to the Surgeon Group will be 50% of the difference between the adjusted current year costs and base year costs, if any.

The Hospital will make an aggregate payment to the Surgeon Group, which distributes its profits to each of its members on a per capita basis. Payments to the Surgeon Group will also be subject to the following limitations:

- If the volume of procedures payable by a Federal health care program in the current year exceeds the volume of like procedures payable by a Federal health care program performed in the base year, there will be no sharing of cost savings for the additional procedures.

- To minimize the surgeons' financial incentive to steer more costly patients to other hospitals, the case severity, ages, and payors of the patient population treated under the Proposed Arrangement will be monitored by a committee composed of representatives of the Requestors, using generally-accepted standards. If there are significant changes from historical measures, the surgeon at issue will be terminated from participation in the Proposed Arrangement.

- The aggregate payment to the Surgeon Group will not exceed 50% of the projected cost savings identified in the Practice Patterns Report.

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[6]The current year will be the twelve-month term of the contract for which the Surgeon Group will be compensated under the Proposed Arrangement.

[7]The "base year" will be the twelve months preceding the effective date of the contract. For purposes of this opinion, the Proposed Arrangement is limited to the one-year term of the contract; accordingly, this opinion is without force and effect with respect to any future renewal or extension of the Proposed Arrangement. Notwithstanding, we note that any renewal or extension of the Proposed Arrangement should incorporate updated base year costs.

The Hospital and the Surgeon Group will document the activities and the payment methodology under the Proposed Arrangement and will make the documentation available to the Secretary of the United States Department of Health and Human Services, upon request. In addition, the Hospital and the Surgeon Group will disclose the Proposed Arrangement to the patient, including the fact that the Surgeon Group's compensation is based on a percentage of the Hospital's cost savings. The disclosure will be made to the patient before the patient is admitted to the Hospital for a procedure covered by the Proposed Arrangement; if pre-admission disclosure is impracticable (e.g., the patient is admitted for an unscheduled procedure or the need for the procedure is determined after admission), the disclosure will be made before the patient consents to the surgery. The disclosures will be in writing, and patients will have an opportunity, if desired, to review details of the Proposed Arrangement, including the specific cost savings measures applicable to the patient's surgery.

II. LEGAL ANALYSIS

Arrangements like the Proposed Arrangement are designed to align incentives by offering physicians a portion of a hospital's cost savings in exchange for implementing cost saving strategies. Under the current reimbursement system, the burden of these costs falls on hospitals, not physicians. Payments to physicians based on cost savings may be intended to motivate them to reduce hospital costs associated with procedures performed by physicians at the hospitals.

Properly structured, arrangements that share cost savings can serve legitimate business and medical purposes. Specifically, properly structured arrangements may increase efficiency and reduce waste, thereby potentially increasing a hospital's profitability. However, such arrangements can potentially influence physician judgment to the detriment of patient care. Our concerns include, but are not limited to, the following: (i) stinting on patient care; (ii) "cherry picking" healthy patients and steering sicker (and more costly) patients to hospitals that do not offer such arrangements; (iii) payments in exchange for patient referrals; and (iv) unfair competition (a "race to the bottom") among hospitals offering cost savings programs to foster physician loyalty and to attract more referrals.

Hospital cost savings programs in general, and the Proposed Arrangement in particular, may implicate at least three Federal legal authorities: (i) the civil monetary penalty for reductions or limitations of direct patient care services provided to Federal health care program beneficiaries, sections 1128A(b)(1)-(2) of the Act; (ii) the anti-kickback statute, section 1128B(b) of the Act; and (iii) the physician self-referral law, section 1877 of the

Act.[8] We address the first two of these authorities; section 1877 of the Act falls outside the scope of the OIG's advisory opinion authority. We express no opinion on the application of section 1877 of the Act to the Proposed Arrangement.

A. The Civil Monetary Penalty, Section 1128A(b)(1)-(2) of the Act

Sections 1128A(b)(1)-(2) of the Act establish a civil monetary penalty ("CMP") against any hospital or critical access hospital that knowingly makes a payment directly or indirectly to a physician (and any physician that receives such a payment) as an inducement to reduce or limit items or services to Medicare or Medicaid beneficiaries under the physician's direct care. Hospitals that make (and physicians that receive) such payments are liable for CMPs of up to $2,000 per patient covered by the payments. See id. There is no requirement that the prohibited payment be tied to a specific patient or to a reduction in medically necessary care. The CMP applies only to reductions or limitations of items or services provided to Medicare and Medicaid fee-for-service beneficiaries.[9]

The CMP prohibits payments by hospitals to physicians that may induce physicians to reduce or limit items or services furnished to their Medicare and Medicaid patients. A threshold inquiry is whether the Proposed Arrangement will induce physicians to reduce or limit items or services. Given the specificity of the Proposed Arrangement, it is possible to review the proposed opportunities for savings individually and evaluate their potential impact on patient care.

Having reviewed the twenty-four individual recommendations, we conclude that, except for the unopened surgical tray items (discussed in more detail below), the recommendations implicate the CMP. Simply put, with respect to the recommendations regarding the disposable cell saver components, the blood cross-matching, the substitution of less costly items, and the standardization of devices, the Proposed Arrangement constitutes an inducement to reduce or limit the current medical practice at

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[8]In addition, nonprofit hospital arrangements raise issues of private inurement and private benefit under the Internal Revenue Service's income tax regulations in connection with section 501(c)(3) of the Internal Revenue Code. See Rev. Rul. 69-383, 1969-2 C.B. 113. We express no opinion on the application of the Internal Revenue Code to the Proposed Arrangement.

[9]Physician incentive arrangements related to Medicare risk-based managed care contracts, similar Medicaid contracts, and Medicare Advantage plans (formerly Medicare + Choice) are subject to regulation by the Secretary pursuant to sections 1876(i)(8), 1903(m)(2)(A)(x), and 1852(j)(4) of the Act (respectively), in lieu of being subject to sections 1128A(b)(1)-(2). See OIG letter regarding hospital-physician incentive plans for Medicare and Medicaid beneficiaries enrolled in managed care plans (dated August 19, 1999), available at http://oig.hhs.gov/fraud/docs/alertsandbulletins/gsletter.htm. See also 42 C.F.R. § 417.479 (Medicare HMOs or competitive medical plans); 42 C.F.R. § 422.208 (Medicare Advantage plans); 42 C.F.R. § 438.6 (Medicaid risk plans).

the Hospital. We recognize that the current medical practice may involve care that exceeds the requirements of medical necessity. However, whether the current medical practice reflects necessity or prudence is irrelevant for purposes of the CMP.

With respect to the recommendations regarding "open as needed" surgical tray items, we reach a different conclusion. To the extent that the sole delay in providing items or services is the insubstantial time it takes to open a package of supplies readily available in the operating room, we believe there will be no perceptible reduction or limitation in the provision of items or services to patients sufficient to trigger the CMP. However, this conclusion does not apply to the disposable cell saver components. Because the cell saver components must be attached to the machine and the machine must be started up, there will be an additional delay in the cell saver's availability beyond merely opening the disposable components. Accordingly, we conclude that the cell saver incentive is subject to the statutory proscription of the CMP.

In sum, while the recommendations for the "open as needed" surgical tray items do not run afoul of the CMP, we find that the CMP would apply to the remaining recommendations involving the cell saver components, the blood cross-matching, the substitutions of less costly items, and the standardization of devices. Notwithstanding, the Proposed Arrangement has several features that, in combination, provide sufficient safeguards so that we would not seek sanctions against the Requestors under sections 1128A(b)(1)-(2) of the Act.

First, the specific cost-saving actions and resulting savings are clearly and separately identified. The transparency of the Proposed Arrangement will allow for public scrutiny and individual physician accountability for any adverse effects of the Proposed Arrangement, including any difference in treatment among patients based on nonclinical indicators. The transparency of the incentives for specific actions and specific procedures will also facilitate accountability through the medical-legal professional liability system.

Second, the Requestors have proffered credible medical support for the position that implementation of the recommendations will not adversely affect patient care. The Proposed Arrangement will be periodically reviewed by the Requestors to confirm that the Proposed Arrangement is not having an adverse impact on clinical care.[10]

Third, the payments under the Proposed Arrangement are based on all surgeries regardless of the patients' insurance coverage, subject to the cap on payment for Federal

[10]We have had the Proposed Arrangement reviewed by an independent medical expert, as well as a government medical expert. Both have concluded that the proposed cost savings measures, as described in the advisory opinion request and supplemental submissions, should not adversely affect patient care. For purposes of this opinion, however, we rely solely on the Requestors' certifications and nothing in this advisory opinion should be construed as an endorsement or conclusion as to the medical propriety of the specific activities being undertaken as part of the Proposed Arrangement.

health care program procedures. Moreover, the surgical procedures to which the Proposed Arrangement applies are not disproportionately performed on Federal health care program beneficiaries. Additionally, the cost savings are calculated on the Hospital's actual out-of-pocket acquisition costs, not an accounting convention.

Fourth, the Proposed Arrangement protects against inappropriate reductions in services by utilizing objective historical and clinical measures to establish baseline thresholds beyond which no savings accrue to the Surgeon Group. The Requestors have certified that these baseline measures are reasonably related to the Hospital's or comparable hospitals' practices and patient populations. These safeguards are action-specific and not simply based on isolated patient outcome data unrelated to the specific changes in operating room practices.

Fifth, the product standardization portion of the Proposed Arrangement further protects against inappropriate reductions in services by ensuring that individual physicians will still have available the same selection of cardiac devices after implementation of the Proposed Arrangement as before. The Proposed Arrangement is designed to produce savings through inherent clinical and fiscal value and not from restricting the availability of devices.

Sixth, the Hospital and the Surgeon Group will provide written disclosures of their involvement in the Proposed Arrangement to patients whose care may be affected by the Proposed Arrangement and will provide patients an opportunity to review the cost savings recommendations prior to admission to the Hospital (or, where pre-admission consent is impracticable, prior to consenting to surgery). While we do not believe that, standing alone, such disclosures offer sufficient protection from program or patient abuse, effective and meaningful disclosure offers some protection against possible abuses of patient trust.[11]

Seventh, the financial incentives under the Proposed Arrangement are reasonably limited in duration and amount.

Eighth, because the Surgeon Group's profits are distributed to its members on a per capita basis, any incentive for an individual surgeon to generate disproportionate cost savings is mitigated.

Our decision not to impose sanctions on the Requestors in connection with the Proposed Arrangement is an exercise of our discretion and is consistent with our Special Advisory Bulletin on "Gainsharing Arrangements and CMPs for Hospital Payments to Physicians to Reduce or Limit Services to Beneficiaries" (July 1999) (the "Special Advisory

[11]Ordinarily, we would expect patient disclosures to be coupled with patient satisfaction surveys that closely monitor patient perceptions of their care. However, in the context of the Proposed Arrangement, which focuses on items and medications used in operating rooms, we believe that patient satisfaction surveys would not be effective.

Bulletin"). We reiterate that the CMP applies to any payment by a hospital to a physician that is intended to induce the reduction or limitation of items or services to Medicare or Medicaid patients under the physician's direct clinical care. The Proposed Arrangement is markedly different from many "gainsharing" plans, particularly those that purport to pay physicians a percentage of generalized cost savings not tied to specific, identifiable cost-lowering activities. Importantly, the Proposed Arrangement sets out the specific actions to be taken and ties the remuneration to the actual, verifiable cost savings attributable to those actions. This transparency allows an assessment of the likely effect of the Proposed Arrangement on quality of care and ensures that the identified actions will be the cause of the savings.

By contrast, many gainsharing plans contain features that heighten the risk that payments will lead to inappropriate reductions or limitations of services. These features include, but are not limited to, the following:

- There is no demonstrable direct connection between individual actions and any reduction in the hospital's out-of-pocket costs (and any corresponding "gainsharing" payment).

- The individual actions that would give rise to the savings are not identified with specificity.

- There are insufficient safeguards against the risk that other, unidentified actions, such as premature hospital discharges, might actually account for any "savings."

- The quality of care indicators are of questionable validity and statistical significance.

- There is no independent verification of cost savings, quality of care indicators, or other essential aspects of the arrangement.

Simply put, many "gainsharing" plans present substantial risks for both patient and program abuse – risks that are not present in the Proposed Arrangement. Given the limited duration and scope of the Proposed Arrangement, the safeguards provide sufficient protections against patient and program abuse. Other arrangements, including those that are longer in duration or more expansive in scope than the Proposed Arrangement, are likely to require additional or different safeguards.

B. The Anti-Kickback Statute

The anti-kickback statute makes it a criminal offense knowingly and willfully to offer, pay, solicit, or receive any remuneration to induce or reward referrals of items or services reimbursable by a Federal health care program. See section 1128B(b) of the Act. Where remuneration is paid purposefully to induce or reward referrals of items or services payable by a Federal health care program, the anti-kickback statute is violated. By its terms, the statute ascribes criminal liability to parties on both sides of an impermissible "kickback" transaction. For purposes of the anti-kickback statute, "remuneration" includes the transfer of anything of value, directly or indirectly, overtly or covertly, in cash or in kind.

The statute has been interpreted to cover any arrangement where one purpose of the remuneration was to obtain money for the referral of services or to induce further referrals. United States v. Kats, 871 F.2d 105 (9th Cir. 1989); United States v. Greber, 760 F.2d 68 (3d Cir.), cert. denied, 474 U.S. 988 (1985). Violation of the statute constitutes a felony punishable by a maximum fine of $25,000, imprisonment up to five years, or both. Conviction will also lead to automatic exclusion from Federal health care programs, including Medicare and Medicaid. Where a party commits an act described in section 1128B(b) of the Act, the OIG may initiate administrative proceedings to impose civil monetary penalties on such party under section 1128A(a)(7) of the Act. The OIG may also initiate administrative proceedings to exclude such party from the Federal health care programs under section 1128(b)(7) of the Act.

The Department of Health and Human Services has promulgated safe harbor regulations that define practices that are not subject to the anti-kickback statute because such practices would be unlikely to result in fraud or abuse. See 42 C.F.R. § 1001.952. The safe harbors set forth specific conditions that, if met, assure entities involved of not being prosecuted or sanctioned for the arrangement qualifying for the safe harbor. However, safe harbor protection is afforded only to those arrangements that precisely meet all of the conditions set forth in the safe harbor.

The safe harbor for personal services and management contracts, 42 C.F.R. §1001.952(d), is potentially applicable to the Proposed Arrangement. In relevant part for purposes of this advisory opinion, the personal services safe harbor requires that the aggregate compensation paid for the services be set in advance and consistent with fair market value in arm's-length transactions. The Proposed Arrangement would not fit in the safe harbor because the Surgeon Group will be paid on a percentage basis, and thus the compensation would not be set in advance. However, the absence of safe harbor protection is not fatal. Instead, the Proposed Arrangement must be subject to case-by-case evaluation.

Like any compensation arrangement between a hospital and a physician who admits or refers patients to such hospital, we are concerned that the Proposed Arrangement could be used to disguise remuneration from the Hospital to reward or induce referrals by the Surgeon Group. Specifically, the Proposed Arrangement could encourage the surgeons to admit Federal health care program patients to the Hospital, since the surgeons would

receive not only their Medicare Part B professional fee, but also, indirectly, a share of the Hospital's payment, depending on cost savings. In other words, the more procedures a surgeon performs at the Hospital, the more money he or she is likely to receive under the Proposed Arrangement.

While we believe the Proposed Arrangement could result in illegal remuneration if the requisite intent to induce referrals were present, we would not impose sanctions in the particular circumstances presented here and as qualified below.

First, the circumstances and safeguards of the Proposed Arrangement reduce the likelihood that the arrangement will be used to attract referring physicians or to increase referrals from existing physicians. Specifically, participation in the Proposed Arrangement will be limited to surgeons already on the medical staff, thus limiting the likelihood that the Proposed Arrangement will attract other surgeons. In addition, the potential savings derived from procedures for Federal health care program beneficiaries will be capped based on the prior year's admissions of Federal health care program beneficiaries. Finally, the contract term will be limited to one year, reducing any incentive to switch facilities, and admissions will be monitored for changes in severity, age, or payor. Thus, while the incentive to refer will not necessarily be eliminated, it will be substantially reduced.

Second, the structure of the Proposed Arrangement eliminates the risk that the Proposed Arrangement will be used to reward cardiologists or other physicians who refer patients to the Surgeon Group or its surgeons. The Surgeon Group is the sole participant in the Proposed Arrangement and is composed entirely of cardiac surgeons; no cardiologists or other physicians are members of the Surgeon Group or share in its profit distributions. Within the Surgeon Group, profits are distributed to its members on a per capita basis, mitigating any incentive for an individual surgeon to generate disproportionate cost savings.

Third, the Proposed Arrangement sets out with specificity the particular actions that will generate the cost savings on which the payments are based. While many of the recommendations in the Practice Patterns Report are simple common sense, they do represent a change in operating room practice, for which the surgeon is responsible and will have liability exposure. While most of the recommendations would appear to present minimal risk, the preparation of the cell saver, blood cross-matching, and product standardization each carry some increased liability risk for the physicians. It is not unreasonable for the surgeon to receive compensation for the increased risk from the proposed change in practice. Moreover, the payments will represent a portion of one year's worth of cost savings and will be limited in amount (i.e., the aggregate cap), duration (i.e., the limited contract term), and scope (i.e., the total savings that can be achieved from the implementation of any one recommendation are limited by appropriate utilization levels). The payments under the Proposed Arrangement do not appear unreasonable, given, among other things, the nature of the actions required of the physicians to implement the twenty-four recommended actions, the specificity of the

payment formula, and the cap on total remuneration to the Surgeon Group.[12] We caution that payments of 50% of cost savings in other arrangements, including multi-year arrangements or arrangements with generalized cost savings formulae, could well lead to a different result.

In light of these circumstances and safeguards, the Proposed Arrangement poses a low risk of fraud or abuse under the anti-kickback statute.

III. CONCLUSION

Notwithstanding the foregoing, we reiterate our concerns regarding many arrangements between hospitals and physicians to share cost savings. Improperly designed or implemented arrangements risk adversely affecting patient care and could be vehicles to disguise payments for referrals. For example, an arrangement that cannot be adequately and accurately measured for quality of care would pose a high risk of fraud or abuse, as would one that rewards physicians based on overall cost savings without accountability for specific cost reduction measures. Moreover, arrangements structured so as to pose a heightened potential for patient steering and unfair competition would be considered suspect. In short, this opinion is predicated on the specific arrangement posed by the Requestors and is limited to that specific arrangement. Other apparently similar arrangements could raise different concerns and lead to a different result.

Based on the facts certified in your request for an advisory opinion and supplemental submissions, we conclude: (i) the Proposed Arrangement would constitute an improper payment to induce reduction or limitation of services pursuant to sections 1128A(b)(1)-(2) of the Act, but that the OIG would not impose sanctions under sections 1128A(b)(1)-(2) on the Requestors in connection with the Proposed Arrangement; and (ii) the Proposed Arrangement would potentially generate prohibited remuneration under the anti-kickback statute, if the requisite intent to induce or reward referrals of Federal health care program business were present, but that the OIG would not impose administrative sanctions on the Requestors under sections 1128(b)(7) or 1128A(a)(7) of the Act (as those sections relate to the commission of acts described in section 1128B(b) of the Act) in connection with the Proposed Arrangement.

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[12]We are precluded by statute from opining on whether fair market value shall be or was paid for goods, services, or property. See 42 U.S.C. § 1320a-7d(b)(3)(A). While the Requestors have certified that the payments under the Proposed Arrangement are consistent with fair market value, we do not rely on that certification in this opinion, nor have we have made an independent fair market value assessment.

IV. LIMITATIONS

The limitations applicable to this opinion include the following:

- This advisory opinion is issued only to [names redacted], the requestors of this opinion. This advisory opinion has no application to, and cannot be relied upon by, any other individual or entity.

- This advisory opinion may not be introduced into evidence in any matter involving an entity or individual that is not a requestor to this opinion.

- This advisory opinion is applicable only to the statutory provisions specifically noted above. No opinion is expressed or implied herein with respect to the application of any other Federal, state, or local statute, rule, regulation, ordinance, or other law that may be applicable to the Proposed Arrangement, including, without limitation, the physician self-referral law, section 1877 of the Act.

- This advisory opinion will not bind or obligate any agency other than the U.S. Department of Health and Human Services.

- This advisory opinion is limited in scope to the specific arrangement described in this letter and has no applicability to other arrangements, even those that appear similar in nature or scope.

- No opinion is expressed herein regarding the liability of any party under the False Claims Act or other legal authorities for any improper billing, claims submission, cost reporting, or related conduct.

This opinion is also subject to any additional limitations set forth at 42 C.F.R. Part 1008.

The OIG will not proceed against the Requestors with respect to any action that is part of the Proposed Arrangement taken in good faith reliance upon this advisory opinion, as long as all of the material facts have been fully, completely, and accurately presented, and the Proposed Arrangement in practice comports with the information provided. The OIG reserves the right to reconsider the questions and issues raised in this advisory opinion and, where the public interest requires, to rescind, modify, or terminate this opinion. In the event that this advisory opinion is modified or terminated, the OIG will not proceed against the Requestors with respect to any action taken in good faith reliance upon this advisory opinion, where all of the relevant facts were fully, completely, and accurately presented, and where such action was promptly discontinued upon notification of the

modification or termination of this advisory opinion. An advisory opinion may be rescinded only if the relevant and material facts have not been fully, completely, and accurately disclosed to the OIG.

Sincerely,

/s/

Lewis Morris
Chief Counsel to the Inspector General

[Appendix A Redacted]

[*We redact certain identifying information and certain potentially privileged, confidential, or proprietary information associated with the individual or entity, unless otherwise approved by the requestors.*]

Issued: February 10, 2005

Posted: February 17, 2005

[names and addresses redacted]

Re: **OIG Advisory Opinion No. 05-02**

Ladies and Gentlemen:

We are writing in response to your request for an advisory opinion concerning a proposed arrangement in which a hospital will share with five cardiology groups a percentage of the hospital's cost savings arising from the cardiologists' implementation of a number of cost reduction measures in certain cardiac catheterization laboratory procedures (the "Proposed Arrangement"). The cost savings will be measured based on the cardiologists' use of specific supplies during designated cardiology procedures. You have inquired whether the Proposed Arrangement would constitute grounds for sanctions arising under: (i) the civil monetary penalty for a hospital's payment to a physician to induce reductions or limitations of services to Medicare or Medicaid beneficiaries under the physician's direct care, sections 1128A(b)(1)-(2) of the Social Security Act (the "Act"); or (ii) the exclusion authority at section 1128(b)(7) of the Act or the civil monetary penalty provision at section 1128A(a)(7) of the Act, as those sections relate to the commission of acts described in section 1128B(b) of the Act, the anti-kickback statute.

You have certified that all of the information provided in your request, including all supplementary letters, is true and correct and constitutes a complete description of the relevant facts and agreements among the parties.

In issuing this opinion, we have relied solely on the facts and information presented to us. We have not undertaken an independent investigation of such information. This opinion is limited to the facts presented. If material facts have not been disclosed or have been misrepresented, this opinion is without force and effect.

Based on the information provided and the totality of the facts as described and certified in your request for an advisory opinion and supplemental submissions, we conclude that: (i) the Proposed Arrangement would constitute an improper payment to induce reduction or limitation of services pursuant to sections 1128A(b)(1)-(2) of the Act, but that the

Office of Inspector General ("OIG") would not impose sanctions on the requestors of this advisory opinion, [names redacted] (the "Requestors"), in connection with the Proposed Arrangement; and (ii) the Proposed Arrangement would potentially generate prohibited remuneration under the anti-kickback statute, if the requisite intent to induce or reward referrals of Federal health care program business were present, but that the OIG would not impose administrative sanctions on the Requestors under sections 1128(b)(7) or 1128A(a)(7) of the Act (as those sections relate to the commission of acts described in section 1128B(b) of the Act) in connection with the Proposed Arrangement.

This opinion may not be relied on by any persons other than the Requestors and is further qualified as set out in Part IV below and in 42 C.F.R. Part 1008.

I. FACTUAL BACKGROUND

A. Parties

The Hospital. [Name redacted] (the "Hospital"), is an acute care hospital in [city and state redacted], that offers a broad range of inpatient and outpatient hospital services, including cardiac catheterization laboratory services. The Hospital is a participating provider in the Medicare and Medicaid programs.

The Cardiology Groups. [Names redacted], (collectively, the "Cardiology Groups," individually, where applicable, the "Cardiology Group") are professional corporations that separately employ physicians duly licensed in [state redacted] who have active medical staff privileges at the Hospital.[1] The Cardiology Groups refer patients to the Hospital for inpatient and outpatient hospital services. Each Cardiology Group will enter into a separate contract with the Hospital that will set forth the projected savings opportunities applicable to the individual Cardiology Group.

The Program Administrator. The Hospital has engaged [name redacted] (the "Program Administrator") to administer the Proposed Arrangement. The Program Administrator will collect data and analyze and manage the Proposed Arrangement.[2] The Hospital will pay the Program Administrator a monthly fixed fee certified by the Requestors to be fair market value in an arm's-length transaction for services to be provided by the Program Administrator under the Proposed Arrangement. The fee will not be tied in any way to cost savings or the Cardiology Groups' compensation under the Proposed Arrangement.

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[1]The Cardiology Groups have members who also practice at other hospitals in the region; however, the Hospital is the primary practice location for most of the cardiologists in the Cardiology Groups.

[2]The Program Administrator has developed software products that measure cost, quality, and utilization on a national basis. The products are certified by both the American College of Cardiology and the Society of Thoracic Surgery.

B. The Proposed Arrangement

Under the Proposed Arrangement, the Hospital will pay each Cardiology Group a share of the first year cost savings directly attributable to specific changes in each Cardiology Group's cardiac catheterization laboratory practices. The majority of the changes involve product standardization. The Program Administrator conducted a study of the historic practices at the Hospital's cardiology department and identified eighteen specific cost-savings opportunities. The results of the Program Administrator's study of each Cardiology Group and the specific cost-savings opportunities for each Group are summarized in a "Practice Patterns Report."[3] The Hospital and each Cardiology Group have reviewed the Practice Patterns Report for medical appropriateness and each has adopted its recommendations and conclusions.

In general, the Practice Patterns Report recommends that the Cardiology Groups change current cardiac catheterization laboratory practices to curb inappropriate use or waste of medical supplies. The eighteen recommendations can be grouped into two categories.

The first category, involving sixteen recommendations, consists of product standardization where medically appropriate. The Practice Patterns Report recommends that each Cardiology Group standardize the types of cardiac catheterization devices (stents, balloons, interventional guidewires and catheters, vascular closure devices, diagnostic devices, pacemakers, and defibrillators) used by the Cardiology Group.[4] Each Cardiology Group would be required to work in conjunction with the Hospital to evaluate and clinically review vendors and products. Each Cardiology Group would agree to use the selected products, where medically appropriate, which may require additional training or changes in clinical practice.

The second category, involving two recommendations, consists of limiting the use of certain vascular closure devices to an "as needed" basis for inpatient coronary interventional procedures and diagnostic procedures. The Requestors have certified that the vascular closure devices will be readily available, albeit unopened, in the procedure room. The Requestors have certified that the reduction in use of vascular closure devices will not adversely affect patient care.

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[3]The Practice Patterns Report for the Cardiology Groups, dated October 2004, is attached to this advisory opinion as Appendix A. This opinion is based on the specific cost savings recommendations and associated facts (e.g., specific floors set for each recommendation) set forth in the Practice Patterns Report as appropriate for the Requestors. Similar cost savings recommendations involving different facts could produce a different result.

[4]We note that the Practice Patterns Report identifies with specificity the vendors and products at issue.

The Proposed Arrangement contains several safeguards intended to protect against inappropriate reductions in services. Importantly, with respect to the product standardization, the Requestors have certified that the individual cardiologists will make a patient-by-patient determination of the most appropriate device and the availability of the full range of devices will not be compromised by the product standardization. The Requestors have further certified that individual physicians will still have available the same selection of devices after implementation of the Proposed Arrangement as before and that the economies gained through the Proposed Arrangement will result from inherent clinical and fiscal value and not from restricting the availability of devices.

With respect to the limitation on use of vascular closure devices, the Proposed Arrangement would utilize objective historical and clinical measures reasonably related to the practices and the patient population at the Hospital to establish a "floor" beyond which no savings would accrue to the Cardiology Groups. For example, according to the Requestors, vascular closure devices for coronary interventional patients are currently utilized at the Hospital on 30% of the cases specified under the Proposed Arrangement. The Program Administrator has determined through analysis of national data that it is reasonable to reduce the use of vascular closure devices to 10% of patients and that this reduction would not adversely impact patient care. Thus, the Cardiology Groups will receive no share of any savings resulting from the reduction of use of vascular closure devices beyond the 10% floor.

According to the Program Administrator, if implemented in accordance with the Practice Patterns Report's specifications, the eighteen recommendations would present substantial cost savings opportunities for the Hospital without adversely impacting the quality of patient care.

The Hospital will enter into a separate contract with each Cardiology Group that will specify the historic costs, base year costs, and projected cost-savings opportunities applicable to each individual group. Under each contract, the Hospital will pay the contracting Cardiology Group 50% of the cost savings achieved by implementing the eighteen recommendations in the Practice Patterns Report, applicable to the contracting Cardiology Group, for a period of one year. At the end of the year, cost savings will be calculated separately for each of the eighteen recommendations for each Group; this will preclude shifting of cost savings and ensure that savings generated by utilization beyond the set targets, as applicable, will not be credited to each Cardiology Group. This payment will constitute the entire compensation paid to each Cardiology Group for services performed under the individual contracts memorializing the Proposed Arrangement. The payment to each Cardiology Group will be calculated using the same formula. For purposes of calculating the payment to each Cardiology Group, the actual costs incurred for the items specified in the eighteen recommendations when used by cardiologists in the Cardiology Group during the specified procedures (the "current year

costs"[5]) will be subtracted from the historic costs for the same items when used during comparable procedures in the base year (the "base year costs"[6]). The current year costs will be adjusted to account for any inappropriate reductions in use of items beyond the targets set in the Practice Patterns Report. The payment to each Cardiology Group will be 50% of the difference between their adjusted current year costs and base year costs, if any.

The Hospital will make an aggregate payment to each Cardiology Group, all of which distribute profits to their members on a per capita basis. Payments to each Cardiology Group will also be subject to the following limitations:

- If the volume of procedures payable by a Federal health care program in the current year exceeds the volume of like procedures payable by a Federal health care program performed in the base year, there will be no sharing of cost savings for the additional procedures.

- To minimize the cardiologists' financial incentive to steer more costly patients to other hospitals, the case severity, ages, and payors of the patient population treated under the Proposed Arrangement will be monitored by a committee composed of representatives of the Requestors, using generally-accepted standards. If there are significant changes from historical measures, the cardiologist at issue will be terminated from participation in the Proposed Arrangement.

- The aggregate payment to each Cardiology Group will not exceed 50% of the projected cost savings identified in the Practice Patterns Report.

The Hospital and the Cardiology Groups will document the activities and the payment methodology under the Proposed Arrangement and will make the documentation available to the Secretary of the United States Department of Health and Human Services, upon request. In addition, the Hospital and the Cardiology Groups will disclose the Proposed Arrangement to the patient, including the fact that the Cardiology Groups' compensation is based on a percentage of the Hospital's cost savings. The disclosure will be made to the patient before the patient is admitted to the Hospital for a procedure

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[5]The current year will be the twelve-month term of the contract for which each of the Cardiology Groups will be compensated under the Proposed Arrangement.

[6]The "base year" will be the twelve months preceding the effective date of the contract. For purposes of this opinion, the Proposed Arrangement is limited to the one-year term of the contract; accordingly, this opinion is without force and effect with respect to any future renewal or extension of the Proposed Arrangement. Notwithstanding, we note that any renewal or extension of the Proposed Arrangement should incorporate updated base year costs.

covered by the Proposed Arrangement; if pre-admission disclosure is impracticable (e.g., the patient is admitted for an unscheduled procedure or the need for the procedure is determined after admission), the disclosure will be made before the patient consents to the procedure. The disclosures will be in writing, and patients will have an opportunity, if desired, to review details of the Proposed Arrangement, including the specific cost savings measures applicable to the patient's procedure.

II. LEGAL ANALYSIS

Arrangements like the Proposed Arrangement are designed to align incentives by offering physicians a portion of a hospital's cost savings in exchange for implementing cost saving strategies. Under the current reimbursement system, the burden of these costs falls on hospitals, not physicians. Payments to physicians based on cost savings may be intended to motivate them to reduce hospital costs associated with procedures performed by physicians at the hospitals.

Properly structured, arrangements that share cost savings can serve legitimate business and medical purposes. Specifically, properly structured arrangements may increase efficiency and reduce waste, thereby potentially increasing a hospital's profitability. However, such arrangements can potentially influence physician judgment to the detriment of patient care. Our concerns include, but are not limited to, the following: (i) stinting on patient care; (ii) "cherry picking" healthy patients and steering sicker (and more costly) patients to hospitals that do not offer such arrangements; (iii) payments in exchange for patient referrals; and (iv) unfair competition (a "race to the bottom") among hospitals offering cost savings programs to foster physician loyalty and to attract more referrals.

Hospital cost savings programs in general, and the Proposed Arrangement in particular, may implicate at least three legal authorities: (i) the civil monetary penalty for reductions or limitations of direct patient care services provided to Federal health care program beneficiaries, sections 1128A(b)(1)-(2) of the Act; (ii) the anti-kickback statute, section 1128B(b) of the Act; and (iii) the physician self-referral law, section 1877 of the Act.[7] We address the first two of these authorities; section 1877 of the Act falls outside the scope of the OIG's advisory opinion authority. We express no opinion on the application of section 1877 of the Act to the Proposed Arrangement.

[7]In addition, nonprofit hospital arrangements raise issues of private inurement and private benefit under the Internal Revenue Service's income tax regulations in connection with section 501(c)(3) of the Internal Revenue Code. See Rev. Rul. 69-383, 1969-2 C.B. 113. We express no opinion on the application of the Internal Revenue Code to the Proposed Arrangement.

A. The Civil Monetary Penalty, Sections 1128A(b)(1)-(2) of the Act

Sections 1128A(b)(1)-(2) of the Act establish a civil monetary penalty ("CMP") against any hospital or critical access hospital that knowingly makes a payment directly or indirectly to a physician (and any physician that receives such a payment) as an inducement to reduce or limit items or services to Medicare or Medicaid beneficiaries under the physician's direct care. Hospitals that make (and physicians that receive) such payments are liable for CMPs of up to $2,000 per patient covered by the payments. See id. There is no requirement that the prohibited payment be tied to a specific patient or to a reduction in medically necessary care. The CMP applies only to reductions or limitations of items or services provided to Medicare and Medicaid fee-for-service beneficiaries.[8]

The CMP prohibits payments by hospitals to physicians that may induce physicians to reduce or limit items or services furnished to their Medicare and Medicaid patients. A threshold inquiry is whether the Proposed Arrangement will induce physicians to reduce or limit items or services. Given the specificity of the Proposed Arrangement, it is possible to review the proposed opportunities for savings individually and evaluate their potential impact on patient care.

Having reviewed the eighteen recommendations, we conclude that the recommendations implicate the CMP. Simply put, the recommendations, under the Proposed Arrangement, regarding standardization of devices and limitations on the use of vascular closure devices constitute an inducement to reduce or limit the current medical practice at the Hospital. Thus, we find that the CMP would apply to the Proposed Arrangement. We recognize that the current medical practice may involve care that exceeds the requirements of medical necessity. However, whether the current medical practice reflects necessity or prudence is irrelevant for purposes of the CMP.

Notwithstanding, the Proposed Arrangement has several features that, in combination, provide sufficient safeguards so that we would not seek sanctions against the Requestors under sections 1128A(b)(1)-(2) of the Act.

First, the specific cost-saving actions and resulting savings are clearly and separately

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[8]Physician incentive arrangements related to Medicare risk-based managed care contracts, similar Medicaid contracts, and Medicare Advantage plans (formerly Medicare + Choice) are subject to regulation by the Secretary pursuant to sections 1876(i)(8), 1903(m)(2)(A)(x), and 1852(j)(4) of the Act (respectively), in lieu of being subject to sections 1128A(b)(1)-(2). See OIG letter regarding hospital-physician incentive plans for Medicare and Medicaid beneficiaries enrolled in managed care plans (dated August 19, 1999), available at http://oig.hhs.gov/fraud/docs/alertsandbulletins/gsletter.htm. See also 42 C.F.R. § 417.479 (Medicare HMOs or competitive medical plans); 42 C.F.R. § 422.208 (Medicare Advantage plans); 42 C.F.R. § 438.6 (Medicaid risk plans).

identified. The transparency of the Proposed Arrangement will allow for public scrutiny and individual physician accountability for any adverse effects of the Proposed Arrangement, including any difference in treatment among patients based on nonclinical indicators. The transparency of the incentives for specific actions and specific procedures will also facilitate accountability through the medical-legal professional liability system.

Second, the Requestors have proffered credible medical support for the position that implementation of the recommendations will not adversely affect patient care. The Proposed Arrangement will be periodically reviewed by the Requestors to confirm that the Proposed Arrangement is not having an adverse impact on clinical care.[9]

Third, the payments under the Proposed Arrangement are based on all procedures regardless of the patients' insurance coverage, subject to the cap on payment for Federal health care program procedures. Moreover, the procedures to which the Proposed Arrangement applies are not disproportionately performed on Federal health care program beneficiaries. Additionally, the cost savings are calculated on the Hospital's actual out-of-pocket acquisition costs, not an accounting convention.

Fourth, the Proposed Arrangement protects against inappropriate reductions in services by utilizing objective historical and clinical measures to establish baseline thresholds beyond which no savings accrue to the Cardiology Groups. The Requestors have certified that these baseline measures are reasonably related to the Hospital's or comparable hospitals' practices and patient populations. These safeguards are action-specific and not simply based on isolated patient outcome data unrelated to the specific changes in catheterization laboratory practices.

Fifth, the product standardization portion of the Proposed Arrangement further protects against inappropriate reductions in services by ensuring that individual physicians will still have available the same selection of devices after implementation of the Proposed Arrangement as before. The Proposed Arrangement is designed to produce savings through inherent clinical and fiscal value and not from restricting the availability of devices.

Sixth, the Hospital and the Cardiology Groups will provide written disclosures of their involvement in the Proposed Arrangement to patients whose care may be affected by the Proposed Arrangement and will provide patients an opportunity to review the cost savings

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[9]We have had the Proposed Arrangement reviewed by a government medical expert, who concluded that the proposed cost savings measures, as described in the advisory opinion request and supplemental submissions, should not adversely affect patient care. For purposes of this opinion, however, we rely solely on the Requestors' certifications and nothing in this advisory opinion should be construed as an endorsement or conclusion as to the medical propriety of the specific activities being undertaken as part of the Proposed Arrangement.

recommendations prior to admission to the Hospital (or, where pre-admission consent is impracticable, prior to consenting to the procedure). While we do not believe that, standing alone, such disclosures offer sufficient protection from program or patient abuse, effective and meaningful disclosure offers some protection against possible abuses of patient trust.[10]

Seventh, the financial incentives under the Proposed Arrangement are reasonably limited in duration and amount.

Eighth, because each Cardiology Group's profits are distributed to its members on a per capita basis, any incentive for an individual cardiologist to generate disproportionate cost savings is mitigated.

Our decision not to impose sanctions on the Requestors in connection with the Proposed Arrangement is an exercise of our discretion and is consistent with our Special Advisory Bulletin on "Gainsharing Arrangements and CMPs for Hospital Payments to Physicians to Reduce or Limit Services to Beneficiaries" (July 1999) (the "Special Advisory Bulletin"). We reiterate that the CMP applies to any payment by a hospital to a physician that is intended to induce the reduction or limitation of items or services to Medicare or Medicaid patients under the physician's direct clinical care. The Proposed Arrangement is markedly different from many "gainsharing" plans, particularly those that purport to pay physicians a percentage of generalized cost savings not tied to specific, identifiable cost-lowering activities. Importantly, the Proposed Arrangement sets out the specific actions to be taken and ties the remuneration to the actual, verifiable cost savings attributable to those actions. This transparency allows an assessment of the likely effect of the Proposed Arrangement on quality of care and ensures that the identified actions will be the cause of the savings.

By contrast, many gainsharing plans contain features that heighten the risk that payments will lead to inappropriate reductions or limitations of services. These features include, but are not limited to, the following:

- There is no demonstrable direct connection between individual actions and any reduction in the hospital's out-of-pocket costs (and any corresponding "gainsharing" payment).

- The individual actions that would give rise to the savings are not identified with specificity.

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[10]Ordinarily, we would expect patient disclosures to be coupled with patient satisfaction surveys that closely monitor patient perceptions of their care. However, in the context of the Proposed Arrangement, which focuses on items and medications used in catheterization laboratory procedures, we believe that patient satisfaction surveys would not be effective.

- There are insufficient safeguards against the risk that other, unidentified actions, such as premature hospital discharges, might actually account for any "savings."

- The quality of care indicators are of questionable validity and statistical significance.

- There is no independent verification of cost savings, quality of care indicators, or other essential aspects of the arrangement.

Simply put, many "gainsharing" plans present substantial risks for both patient and program abuse – risks that are not present in the Proposed Arrangement. Given the limited duration and scope of the Proposed Arrangement, the safeguards provide sufficient protections against patient and program abuse. Other arrangements, including those that are longer in duration or more expansive in scope than the Proposed Arrangement, are likely to require additional or different safeguards.

B. The Anti-Kickback Statute

The anti-kickback statute makes it a criminal offense knowingly and willfully to offer, pay, solicit, or receive any remuneration to induce or reward referrals of items or services reimbursable by a Federal health care program. See section 1128B(b) of the Act. Where remuneration is paid purposefully to induce or reward referrals of items or services payable by a Federal health care program, the anti-kickback statute is violated. By its terms, the statute ascribes criminal liability to parties on both sides of an impermissible "kickback" transaction. For purposes of the anti-kickback statute, "remuneration" includes the transfer of anything of value, directly or indirectly, overtly or covertly, in cash or in kind.

The statute has been interpreted to cover any arrangement where one purpose of the remuneration was to obtain money for the referral of services or to induce further referrals. United States v. Kats, 871 F.2d 105 (9th Cir. 1989); United States v. Greber, 760 F.2d 68 (3d Cir.), cert. denied, 474 U.S. 988 (1985). Violation of the statute constitutes a felony punishable by a maximum fine of $25,000, imprisonment up to five years, or both. Conviction will also lead to automatic exclusion from Federal health care programs, including Medicare and Medicaid. Where a party commits an act described in section 1128B(b) of the Act, the OIG may initiate administrative proceedings to impose civil monetary penalties on such party under section 1128A(a)(7) of the Act. The OIG may also initiate administrative proceedings to exclude such party from the Federal health care programs under section 1128(b)(7) of the Act.

The Department of Health and Human Services has promulgated safe harbor regulations that define practices that are not subject to the anti-kickback statute because such

practices would be unlikely to result in fraud or abuse. See 42 C.F.R. § 1001.952. The safe harbors set forth specific conditions that, if met, assure entities involved of not being prosecuted or sanctioned for the arrangement qualifying for the safe harbor. However, safe harbor protection is afforded only to those arrangements that precisely meet all of the conditions set forth in the safe harbor.

The safe harbor for personal services and management contracts, 42 C.F.R. §1001.952(d), is potentially applicable to the Proposed Arrangement. In relevant part for purposes of this advisory opinion, the personal services safe harbor requires that the aggregate compensation paid for the services be set in advance and consistent with fair market value in arm's-length transactions. The Proposed Arrangement would not fit in the safe harbor because the Cardiology Groups will be paid on a percentage basis, and thus the compensation would not be set in advance. However, the absence of safe harbor protection is not fatal. Instead, the Proposed Arrangement must be subject to case-by-case evaluation.

Like any compensation arrangement between a hospital and a physician who admits or refers patients to such hospital, we are concerned that the Proposed Arrangement could be used to disguise remuneration from the Hospital to reward or induce referrals by the Cardiology Groups. Specifically, the Proposed Arrangement could encourage the cardiologists to admit Federal health care program patients to the Hospital, since the cardiologists would receive not only their Medicare Part B professional fee, but also, indirectly, a share of the Hospital's payment, depending on cost savings. In other words, the more procedures a cardiologist performs at the Hospital, the more money he or she is likely to receive under the Proposed Arrangement.

While we believe the Proposed Arrangement could result in illegal remuneration if the requisite intent to induce referrals were present, we would not impose sanctions in the particular circumstances presented here and as qualified below.

First, the circumstances and safeguards of the Proposed Arrangement reduce the likelihood that the arrangement will be used to attract referring physicians or to increase referrals from existing physicians. Specifically, participation in the Proposed Arrangement will be limited to cardiologists already on the medical staff, thus limiting the likelihood that the Proposed Arrangement will attract other cardiologists. In addition, the potential savings derived from procedures for Federal health care program beneficiaries will be capped based on the prior year's admissions of Federal health care program beneficiaries. Finally, the contract term will be limited to one year, reducing any incentive to switch facilities, and admissions will be monitored for changes in severity, age, or payor. Thus, while the incentive to refer will not necessarily be eliminated, it will be substantially reduced.

Second, the structure of the Proposed Arrangement eliminates the risk that the Proposed Arrangement will be used to reward surgeons or other physicians who refer patients to the

Cardiology Groups or their cardiologists. The Cardiology Groups are the sole participants in the Proposed Arrangement and are composed entirely of cardiologists; no surgeons or other physicians are members of the Cardiology Groups or share in its profit distributions. Within the Cardiology Groups, profits are distributed to their members on a per capita basis, mitigating any incentive for an individual cardiologist to generate disproportionate cost savings.

Third, the Proposed Arrangement sets out with specificity the particular actions that will generate the cost savings on which the payments are based. The recommendations in the Practice Patterns Report represent a change in cardiac catheterization laboratory procedure, for which the cardiologist is responsible and will have liability exposure. Both the product standardization and the limitation on vascular closure devices carry some increased liability risk for the physicians. It is not unreasonable for the cardiologist to receive compensation for the increased risk from the proposed change in practice. Moreover, the payments will represent a portion of one year's worth of cost savings and will be limited in amount (i.e., the aggregate cap), duration (i.e., the limited contract term), and scope (i.e., the total savings that can be achieved from the implementation of any one recommendation are limited by appropriate utilization levels). The payments under the Proposed Arrangement do not appear unreasonable, given, among other things, the nature of the actions required of the physicians to implement the eighteen recommended actions, the specificity of the payment formula, and the cap on total remuneration to each of the Cardiology Groups.[11] We caution that payments of 50% of cost savings in other arrangements, including multi-year arrangements or arrangements with generalized cost savings formulae, could well lead to a different result.

In light of these circumstances and safeguards, the Proposed Arrangement poses a low risk of fraud or abuse under the anti-kickback statute.

III. CONCLUSION

Notwithstanding the foregoing, we reiterate our concerns regarding many arrangements between hospitals and physicians to share cost savings. Improperly designed or implemented arrangements risk adversely affecting patient care and could be vehicles to disguise payments for referrals. For example, an arrangement that cannot be adequately and accurately measured for quality of care would pose a high risk of fraud or abuse, as would one that rewards physicians based on overall cost savings without accountability for specific cost reduction measures. Moreover, arrangements structured so as to pose a heightened potential for patient steering and unfair competition would be considered

[11]We are precluded by statute from opining on whether fair market value shall be or was paid for goods, services, or property. See 42 U.S.C. § 1320a-7d(b)(3)(A). While the Requestors have certified that the payments under the Proposed Arrangement are consistent with fair market value, we do not rely on that certification in this opinion, nor have we have made an independent fair market value assessment.

suspect. In short, this opinion is predicated on the specific arrangement posed by the Requestors and is limited to that specific arrangement. Other apparently similar arrangements could raise different concerns and lead to a different result.

Based on the facts certified in your request for an advisory opinion and supplemental submissions, we conclude: (i) the Proposed Arrangement would constitute an improper payment to induce reduction or limitation of services pursuant to sections 1128A(b)(1)-(2) of the Act, but that the OIG would not impose sanctions under sections 1128A(b)(1)-(2) on the Requestors in connection with the Proposed Arrangement; and (ii) the Proposed Arrangement would potentially generate prohibited remuneration under the anti-kickback statute, if the requisite intent to induce or reward referrals of Federal health care program business were present, but that the OIG would not impose administrative sanctions on the Requestors under sections 1128(b)(7) or 1128A(a)(7) of the Act (as those sections relate to the commission of acts described in section 1128B(b) of the Act) in connection with the Proposed Arrangement.

IV. LIMITATIONS

The limitations applicable to this opinion include the following:

- This advisory opinion is issued only to [names redacted], the requestors of this opinion. This advisory opinion has no application to, and cannot be relied upon by, any other individual or entity.

- This advisory opinion may not be introduced into evidence in any matter involving an entity or individual that is not a requestor to this opinion.

- This advisory opinion is applicable only to the statutory provisions specifically noted above. No opinion is expressed or implied herein with respect to the application of any other Federal, state, or local statute, rule, regulation, ordinance, or other law that may be applicable to the Proposed Arrangement, including, without limitation, the physician self-referral law, section 1877 of the Act.

- This advisory opinion will not bind or obligate any agency other than the U.S. Department of Health and Human Services.

- This advisory opinion is limited in scope to the specific arrangement described in this letter and has no applicability to other arrangements, even those that appear similar in nature or scope.

- No opinion is expressed herein regarding the liability of any party under the False Claims Act or other legal authorities for any improper billing, claims submission, cost reporting, or related conduct.

This opinion is also subject to any additional limitations set forth at 42 C.F.R. Part 1008.

The OIG will not proceed against the Requestors with respect to any action that is part of the Proposed Arrangement taken in good faith reliance upon this advisory opinion, as long as all of the material facts have been fully, completely, and accurately presented, and the Proposed Arrangement in practice comports with the information provided. The OIG reserves the right to reconsider the questions and issues raised in this advisory opinion and, where the public interest requires, rescind, modify, or terminate this opinion. In the event that this advisory opinion is modified or terminated, the OIG will not proceed against the Requestors with respect to any action taken in good faith reliance upon this advisory opinion, where all of the relevant facts were fully, completely, and accurately presented, and where such action was promptly discontinued upon notification of the modification or termination of this advisory opinion. An advisory opinion may be rescinded only if the relevant and material facts have not been fully, completely, and accurately disclosed to the OIG.

Sincerely,

/s/

Lewis Morris
Chief Counsel to the Inspector General

[Appendix A Redacted]

[*We redact certain identifying information and certain potentially privileged, confidential, or proprietary information associated with the individual or entity, unless otherwise approved by the requestors.*]

Issued: February 10, 2005

Posted: February 17, 2005

[names and addresses redacted]

Re: **OIG Advisory Opinion No. 05-03**

Ladies and Gentlemen:

We are writing in response to your request for an advisory opinion concerning a proposed arrangement in which a hospital will share with a group of cardiac surgeons a percentage of the hospital's cost savings arising from the surgeons' implementation of a number of cost reduction measures in certain surgical procedures (the "Proposed Arrangement"). The cost savings will be measured based on the surgeons' use of specific supplies during designated cardiac surgery procedures. You have inquired whether the Proposed Arrangement would constitute grounds for sanctions arising under: (i) the civil monetary penalty for a hospital's payment to a physician to induce reductions or limitations of services to Medicare or Medicaid beneficiaries under the physician's direct care, sections 1128A(b)(1)-(2) of the Social Security Act (the "Act"); or (ii) the exclusion authority at section 1128(b)(7) of the Act or the civil monetary penalty provision at section 1128A(a)(7) of the Act, as those sections relate to the commission of acts described in section 1128B(b) of the Act, the anti-kickback statute.

You have certified that all of the information provided in your request, including all supplementary letters, is true and correct and constitutes a complete description of the relevant facts and agreements among the parties.

In issuing this opinion, we have relied solely on the facts and information presented to us. We have not undertaken an independent investigation of such information. This opinion is limited to the facts presented. If material facts have not been disclosed or have been misrepresented, this opinion is without force and effect.

Based on the information provided and the totality of the facts as described and certified in your request for an advisory opinion and supplemental submissions, we conclude that: (i) the Proposed Arrangement would constitute an improper payment to induce reduction or limitation of services pursuant to sections 1128A(b)(1)-(2) of the Act, but that the Office of Inspector General ("OIG") would not impose sanctions on the requestors of this

advisory opinion, [names redacted] (collectively, the "Requestors"), in connection with the Proposed Arrangement; and (ii) the Proposed Arrangement would potentially generate prohibited remuneration under the anti-kickback statute, if the requisite intent to induce or reward referrals of Federal health care program business were present, but that the OIG would not impose administrative sanctions on the Requestors under sections 1128(b)(7) or 1128A(a)(7) of the Act (as those sections relate to the commission of acts described in section 1128B(b) of the Act) in connection with the Proposed Arrangement.

This opinion may not be relied on by any persons other than the Requestors and is further qualified as set out in Part IV below and in 42 C.F.R. Part 1008.

I. FACTUAL BACKGROUND

A. Parties

The Hospital. [Name redacted] (the "Hospital") is an acute care hospital in [city and state redacted] that offers a broad range of inpatient and outpatient hospital services, including cardiac surgery services. The Hospital is a participating provider in the Medicare and Medicaid programs.

The Surgical Group. [Name redacted], (the "Surgical Group") is a professional association composed exclusively of cardiac surgeons who are licensed in [state redacted] and have active medical staff privileges at the Hospital. The cardiac surgeons refer patients to the Hospital for inpatient and outpatient hospital services. The Surgical Group is the only group of cardiac surgeons that practices at the Hospital and performs 100% of the Hospital's cardiac surgery.

The Program Administrator. The Hospital has engaged [name redacted] (the "Program Administrator") to administer the Proposed Arrangement. The Program Administrator will collect data and analyze and manage the Proposed Arrangement.[1] The Hospital will pay the Program Administrator a monthly fixed fee certified by the Requestors to be fair market value in an arm's-length transaction for services to be provided by the Program Administrator under the Proposed Arrangement. The fee will not be tied in any way to cost savings or the Surgical Group's compensation under the Proposed Arrangement.

B. The Proposed Arrangement

Under the Proposed Arrangement, the Hospital will pay the Surgical Group a share of the first year cost savings directly attributable to specific changes in the Surgical Group's operating room practices. The Program Administrator conducted a study of the historic practices at the Hospital's cardiac surgery department and identified twenty-nine specific

[1]The Program Administrator has developed software products that measure cost, quality, and utilization on a national basis. The products are certified by both the American College of Cardiology and the Society of Thoracic Surgery.

cost-savings opportunities. The results of the Program Administrator's study of the Surgical Group and the specific cost-savings opportunities are summarized in a "Practice Patterns Report."[2] The Hospital and the Surgical Group have reviewed the Practice Patterns Report for medical appropriateness and each has adopted its recommendations and conclusions.

In general, the Practice Patterns Report recommends that the Surgical Group change its current operating room practices to curb the inappropriate use or waste of medical supplies. The Practice Patterns Report identifies twenty-nine specific recommendations that can be roughly grouped into the following four categories.

The first category consists of thirteen recommendations that involve opening packaged items only as needed during a procedure. Most of these "open as needed" items are surgical tray or comparable supplies. These items will be readily available, albeit unopened, in the operating room. One "open as needed" recommendation involves not opening disposable components of the cell saver unit until a patient experiences excessive bleeding. The Requestors have certified that the resulting delay in cell saver readiness should not exceed two to five minutes and will not adversely affect patient care.

The second category is similar and involves performing blood cross-matching only as needed. The Requestors have certified that all patients would be typed and screened prior to the procedure, with a cross-match being performed only when a patient requires a transfusion. The Hospital does not outsource its blood supply. The Requestors have certified that the resulting delay in blood readiness should be minimal when a cross match is necessary and that the delay will not adversely affect patient care.

The third category, involving fourteen recommendations, consists of the substitution, in whole or in part, of less costly items for items currently being used by the surgeons (hereafter, the "product substitution" recommendations). The identified substitutions[3] have no appreciable clinical significance (e.g. slush drape, wrist splints, armboards, aortic punches, or suture boots). For example, wrist splints or armboards are used for support and protection after insertion of a radial artery line. Under one recommendation, surgeons would be asked to utilize a less expensive wrist splint or armboard that has similar characteristics to the surgeons' historic preference.

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[2]The Practice Patterns Report for the Surgical Group, dated October 2004, is attached to this advisory opinion as Appendix A. This opinion is based on the specific cost savings recommendations and associated facts (e.g., specific floors set for each recommendation) set forth in the Practice Patterns Report as appropriate for the Requestors. Similar cost savings recommendations involving different facts could produce a different result.

[3]The Practice Patterns Report clearly identifies with specificity the items and products at issue for each proposed product substitution recommendation.

The final category involves product standardization of certain cardiac heart valves where medically appropriate. For this category, the Surgical Group would be required to work in conjunction with the Hospital to evaluate and clinically review vendors and products.[4] The Surgical Group would agree to use the selected products where medically appropriate, which may require additional training or changes in clinical practice.

The Proposed Arrangement contains several safeguards intended to protect against inappropriate reductions in services. With respect to the cell saver and blood cross-matching recommendations, the Proposed Arrangement would utilize objective historical and clinical measures reasonably related to the practices and the patient population at the Hospital, and in some cases, national averages to establish a "floor" beyond which no savings would accrue to the Surgical Group.

For example, the cell saver is currently set-up for 100% of the cases, but is utilized in approximately 5% of the cardiac procedures specified under the Proposed Arrangement. Accordingly, the Surgical Group will receive no share of any savings resulting from any reductions in cell saver use for cases beyond the established 10% floor set by the Program Administrator based upon national averages. Similarly, blood cross-matching is currently performed for 100% of the cases, with less than 50% of the cases actually resulting in a transfusion. Thus, the Surgical Group will receive no share of any savings resulting from the reduction of blood cross-matching beyond the 50% floor. With respect to the product substitution recommendations in the Proposed Arrangement, the Practice Patterns Report clearly identifies with specificity each substitution recommendation under this category. No floors will be set, because the identified substitutions will have no appreciable clinical significance.[5]

Importantly, with respect to the product standardization recommendations for cardiac devices, the Requestors have certified that the individual surgeons will make a patient-by-patient determination of the most appropriate device and the availability of the full range of cardiac devices will not be compromised by the product standardization. The Requestors have further certified that individual physicians will still have available the same selection of devices after implementation of the Proposed Arrangement as before and that the economies gained through the Proposed Arrangement will result from inherent clinical and fiscal value and not from restricting the availability of devices.

According to the Program Administrator, if implemented in accordance with the Practice Patterns Report's specifications, the twenty-nine recommendations would present substantial cost savings opportunities for the Hospital without adversely impacting the

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[4]We note that the Practice Patterns Report identifies with specificity the vendors and products at issue.

[5]We note that for product substitution recommendations that have clinical significance, we would require additional safeguards, including, for example, the establishment of appropriate quality thresholds beyond which no cost savings would be credited.

quality of patient care.

The Hospital will pay the Surgical Group 50% of the cost savings achieved by implementing the twenty-nine recommendations in the Practice Patterns Report for a period of one year. At the end of the year, cost savings will be calculated separately for each of the twenty-nine recommendations; this will preclude shifting of cost savings and ensure that savings generated by utilization beyond the set targets, as applicable, will not be credited to the Surgical Group. This payment will constitute the entire compensation paid to the Surgical Group for services performed under the contract memorializing the Proposed Arrangement between the Surgical Group and the Hospital. For purposes of calculating the payment to the Surgical Group, the cost savings will be calculated by subtracting the actual costs incurred for the items specified in the twenty-nine recommendations when used by surgeons in the Surgical Group during the specified surgical procedures (the "current year costs"[6]) from the historic costs for the same items when used during comparable surgical procedures in the base year (the "base year costs"[7]). The current year costs will be adjusted to account for any inappropriate reductions in use of items beyond the targets set in the Practice Patterns Report. The payment to the Surgical Group will be 50% of the difference between the adjusted current year costs and base year costs, if any.

The Hospital will make an aggregate payment to the Surgical Group, which distributes its profits to each of its members on a per capita basis. Payments to the Surgical Group will also be subject to the following limitations:

- If the volume of procedures payable by a Federal health care program in the current year exceeds the volume of like procedures payable by a Federal health care program performed in the base year, there will be no sharing of cost savings for the additional procedures.

- To minimize the surgeons' financial incentive to steer more costly patients to other hospitals, the case severity, ages, and payors of the patient population treated under the Proposed Arrangement will be monitored by a committee composed of representatives of the Requestors, using generally-accepted standards. If there are significant changes from historical measures, the surgeon at issue will be terminated from participation in the Proposed Arrangement.

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[6]The current year will be the twelve-month term of the contract for which the Surgical Group will be compensated under the Proposed Arrangement.

[7]The "base year" will be the twelve months preceding the effective date of the contract. For purposes of this opinion, the Proposed Arrangement is limited to the one-year term of the contract; accordingly, this opinion is without force and effect with respect to any future renewal or extension of the Proposed Arrangement. Notwithstanding, we note that any renewal or extension of the Proposed Arrangement should incorporate updated base year costs.

- The aggregate payment to the Surgical Group will not exceed 50% of the projected cost savings identified in the Practice Patterns Report.

The Hospital and the Surgical Group will document the activities and the payment methodology under the Proposed Arrangement and will make the documentation available to the Secretary of the United States Department of Health and Human Services, upon request. In addition, the Hospital and the Surgical Group will disclose the Proposed Arrangement to the patient, including the fact that the Surgical Group's compensation is based on a percentage of the Hospital's cost savings. The disclosure will be made to the patient before the patient is admitted to the Hospital for a procedure covered by the Proposed Arrangement; if pre-admission disclosure is impracticable (e.g., the patient is admitted for an unscheduled procedure or the need for the procedure is determined after admission), the disclosure will be made before the patient consents to the surgery. The disclosures will be in writing, and patients will have an opportunity, if desired, to review details of the Proposed Arrangement, including the specific cost savings measures applicable to the patient's surgery.

II. LEGAL ANALYSIS

Arrangements like the Proposed Arrangement are designed to align incentives by offering physicians a portion of a hospital's cost savings in exchange for implementing cost saving strategies. Under the current reimbursement system, the burden of these costs falls on hospitals, not physicians. Payments to physicians based on cost savings may be intended to motivate them to reduce hospital costs associated with procedures performed by physicians at the hospitals.

Properly structured, arrangements that share cost savings can serve legitimate business and medical purposes. Specifically, properly structured arrangements may increase efficiency and reduce waste, thereby potentially increasing a hospital's profitability. However, such arrangements can potentially influence physician judgment to the detriment of patient care. Our concerns include, but are not limited to, the following:
(i) stinting on patient care; (ii) "cherry picking" healthy patients and steering sicker (and more costly) patients to hospitals that do not offer such arrangements; (iii) payments in exchange for patient referrals; and (iv) unfair competition (a "race to the bottom") among hospitals offering cost savings programs to foster physician loyalty and to attract more referrals.

Hospital cost savings programs in general, and the Proposed Arrangement in particular, may implicate at least three Federal legal authorities: (i) the civil monetary penalty for reductions or limitations of direct patient care services provided to Federal health care program beneficiaries, sections 1128A(b)(1)-(2) of the Act; (ii) the anti-kickback statute, section 1128B(b) of the Act; and (iii) the physician self-referral law, section 1877 of the

Act.[8] We address the first two of these authorities; section 1877 of the Act falls outside the scope of the OIG's advisory opinion authority. We express no opinion on the application of section 1877 of the Act to the Proposed Arrangement.

A. The Civil Monetary Penalty, Sections 1128A(b)(1)-(2) of the Act

Sections 1128A(b)(1)-(2) of the Act establish a civil monetary penalty ("CMP") against any hospital or critical access hospital that knowingly makes a payment directly or indirectly to a physician (and any physician that receives such a payment) as an inducement to reduce or limit items or services to Medicare or Medicaid beneficiaries under the physician's direct care. Hospitals that make (and physicians that receive) such payments are liable for CMPs of up to $2,000 per patient covered by the payments. See id. There is no requirement that the prohibited payment be tied to a specific patient or to a reduction in medically necessary care. The CMP applies only to reductions or limitations of items or services provided to Medicare and Medicaid fee-for-service beneficiaries.[9]

The CMP prohibits payments by hospitals to physicians that may induce physicians to reduce or limit items or services furnished to their Medicare and Medicaid patients. A threshold inquiry is whether the Proposed Arrangement will induce physicians to reduce or limit items or services. Given the specificity of the Proposed Arrangement, it is possible to review the proposed opportunities for savings individually and evaluate their potential impact on patient care.

Having reviewed the twenty-nine individual recommendations, we conclude that, except for the unopened surgical tray items and the product substitutions (discussed in more detail below), the recommendations implicate the CMP. Simply put, with respect to the recommendations regarding the disposable cell saver components, the blood cross-matching, and the standardization of devices, the Proposed Arrangement constitutes an inducement to reduce or limit the current medical practice at the Hospital. We recognize that the current medical practice may involve care that exceeds the requirements of

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[8]In addition, nonprofit hospital arrangements raise issues of private inurement and private benefit under the Internal Revenue Service's income tax regulations in connection with section 501(c)(3) of the Internal Revenue Code. See Rev. Rul. 69-383, 1969-2 C.B. 113. We express no opinion on the application of the Internal Revenue Code to the Proposed Arrangement.

[9]Physician incentive arrangements related to Medicare risk-based managed care contracts, similar Medicaid contracts, and Medicare Advantage plans (formerly Medicare + Choice) are subject to regulation by the Secretary pursuant to sections 1876(i)(8), 1903(m)(2)(A)(x), and 1852(j)(4) of the Act (respectively), in lieu of being subject to sections 1128A(b)(1)-(2). See OIG letter regarding hospital-physician incentive plans for Medicare and Medicaid beneficiaries enrolled in managed care plans (dated August 19, 1999), available at http://oig.hhs.gov/fraud/docs/alertsandbulletins/gsletter.htm. See also 42 C.F.R. § 417.479 (Medicare HMOs or competitive medical plans); 42 C.F.R. § 422.208 (Medicare Advantage plans); 42 C.F.R. § 438.6 (Medicaid risk plans).

medical necessity. However, whether the current medical practice reflects necessity or prudence is irrelevant for purposes of the CMP.

With respect to the recommendations regarding "open as needed" surgical tray items and product substitutions, we reach a different conclusion. To the extent that the sole delay in providing items or services is the insubstantial time it takes to open a package of supplies readily available in the operating room, we believe there will be no perceptible reduction or limitation in the provision of items or services to patients sufficient to trigger the CMP. However, this conclusion does not apply to the disposable cell saver components. Because the cell saver components must be attached to the machine and the machine must be started up, there will be an additional delay in the cell saver's availability beyond merely opening the disposable components. Accordingly, we conclude that the cell saver incentive is subject to the statutory proscription of the CMP. With respect to the specific product substitution recommendations, the identified substitutions will have no appreciable clinical significance; therefore, we believe there will be no perceptible reduction or limitation in the provision of items or services to patients sufficient to trigger the CMP.

In sum, while the recommendations for the "open as needed" surgical tray items and the specific product substitutions do not run afoul of the CMP, we find that the CMP would apply to the remaining recommendations involving the cell saver components, blood cross-matching, and the standardization of devices. Notwithstanding, the Proposed Arrangement has several features that, in combination, provide sufficient safeguards so that we would not seek sanctions against the Requestors under sections 1128A(b)(1)-(2) of the Act.

First, the specific cost-saving actions and resulting savings are clearly and separately identified. The transparency of the Proposed Arrangement will allow for public scrutiny and individual physician accountability for any adverse effects of the Proposed Arrangement, including any difference in treatment among patients based on nonclinical indicators. The transparency of the incentives for specific actions and specific procedures will also facilitate accountability through the medical-legal professional liability system.

Second, the Requestors have proffered credible medical support for the position that implementation of the recommendations will not adversely affect patient care. The Proposed Arrangement will be periodically reviewed by the Requestors to confirm that the Proposed Arrangement is not having an adverse impact on clinical care.[10]

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[10]We have had the Proposed Arrangement reviewed by an independent medical expert, as well as a government medical expert. Both have concluded that the proposed cost savings measures, as described in the advisory opinion request and supplemental submissions, should not adversely affect patient care. For purposes of this opinion, however, we rely solely on the Requestors' certifications and nothing in this advisory opinion should be construed as an endorsement or conclusion as to the medical propriety of the specific activities being undertaken as part of the Proposed Arrangement.

Third, the payments under the Proposed Arrangement are based on all surgeries regardless of the patients' insurance coverage, subject to the cap on payment for Federal health care program procedures. Moreover, the surgical procedures to which the Proposed Arrangement applies are not disproportionately performed on Federal health care program beneficiaries. Additionally, the cost savings are calculated on the Hospital's actual out-of-pocket acquisition costs, not an accounting convention.

Fourth, the Proposed Arrangement protects against inappropriate reductions in services by utilizing objective historical and clinical measures to establish baseline thresholds beyond which no savings accrue to the Surgical Group. The Requestors have certified that these baseline measures are reasonably related to the Hospital's or comparable hospitals' practices and patient populations. These safeguards are action-specific and not simply based on isolated patient outcome data unrelated to the specific changes in operating room practices.

Fifth, the product standardization portion of the Proposed Arrangement further protects against inappropriate reductions in services by ensuring that individual physicians will still have available the same selection of devices after implementation of the Proposed Arrangement as before. The Proposed Arrangement is designed to produce savings through inherent clinical and fiscal value and not from restricting the availability of devices.

Sixth, the Hospital and the Surgical Group will provide written disclosures of their involvement in the Proposed Arrangement to patients whose care may be affected by the Proposed Arrangement and will provide patients an opportunity to review the cost savings recommendations prior to admission to the Hospital (or, where pre-admission consent is impracticable, prior to consenting to surgery). While we do not believe that, standing alone, such disclosures offer sufficient protection from program or patient abuse, effective and meaningful disclosure offers some protection against possible abuses of patient trust.[11]

Seventh, the financial incentives under the Proposed Arrangement are reasonably limited in duration and amount.

Eighth, because the Surgical Group's profits are distributed to its members on a per capita basis, any incentive for an individual surgeon to generate disproportionate cost savings is mitigated.

Our decision not to impose sanctions on the Requestors in connection with the Proposed Arrangement is an exercise of our discretion and is consistent with our Special Advisory Bulletin on "Gainsharing Arrangements and CMPs for Hospital Payments to Physicians to Reduce or Limit Services to Beneficiaries" (July 1999) (the "Special Advisory Bulletin").

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[11]Ordinarily, we would expect patient disclosures to be coupled with patient satisfaction surveys that closely monitor patient perceptions of their care. However, in the context of the Proposed Arrangement, which focuses on items used in operating rooms, we believe that patient satisfaction surveys would not be effective.

We reiterate that the CMP applies to any payment by a hospital to a physician that is intended to induce the reduction or limitation of items or services to Medicare or Medicaid patients under the physician's direct clinical care. The Proposed Arrangement is markedly different from many "gainsharing" plans, particularly those that purport to pay physicians a percentage of generalized cost savings not tied to specific, identifiable cost-lowering activities. Importantly, the Proposed Arrangement sets out the specific actions to be taken and ties the remuneration to the actual, verifiable cost savings attributable to those actions. This transparency allows an assessment of the likely effect of the Proposed Arrangement on quality of care and ensures that the identified actions will be the cause of the savings.

By contrast, many gainsharing plans contain features that heighten the risk that payments will lead to inappropriate reductions or limitations of services. These features include, but are not limited to, the following:

- There is no demonstrable direct connection between individual actions and any reduction in the hospital's out-of-pocket costs (and any corresponding "gainsharing" payment).

- The individual actions that would give rise to the savings are not identified with specificity.

- There are insufficient safeguards against the risk that other, unidentified actions, such as premature hospital discharges, might actually account for any "savings."

- The quality of care indicators are of questionable validity and statistical significance.

- There is no independent verification of cost savings, quality of care indicators, or other essential aspects of the arrangement.

Simply put, many "gainsharing" plans present substantial risks for both patient and program abuse – risks that are not present in the Proposed Arrangement. Given the limited duration and scope of the Proposed Arrangement, the safeguards provide sufficient protections against patient and program abuse. Other arrangements, including those that are longer in duration or more expansive in scope than the Proposed Arrangement, are likely to require additional or different safeguards.

B. The Anti-Kickback Statute

The anti-kickback statute makes it a criminal offense knowingly and willfully to offer, pay, solicit, or receive any remuneration to induce or reward referrals of items or services reimbursable by a Federal health care program. See section 1128B(b) of the Act. Where remuneration is paid purposefully to induce or reward referrals of items or services payable by a Federal health care program, the anti-kickback statute is violated. By its terms, the statute ascribes criminal liability to parties on both sides of an impermissible

"kickback" transaction. For purposes of the anti-kickback statute, "remuneration" includes the transfer of anything of value, directly or indirectly, overtly or covertly, in cash or in kind.

The statute has been interpreted to cover any arrangement where one purpose of the remuneration was to obtain money for the referral of services or to induce further referrals. United States v. Kats, 871 F.2d 105 (9th Cir. 1989); United States v. Greber, 760 F.2d 68 (3d Cir.), cert. denied, 474 U.S. 988 (1985). Violation of the statute constitutes a felony punishable by a maximum fine of $25,000, imprisonment up to five years, or both. Conviction will also lead to automatic exclusion from Federal health care programs, including Medicare and Medicaid. Where a party commits an act described in section 1128B(b) of the Act, the OIG may initiate administrative proceedings to impose civil monetary penalties on such party under section 1128A(a)(7) of the Act. The OIG may also initiate administrative proceedings to exclude such party from the Federal health care programs under section 1128(b)(7) of the Act.

The Department of Health and Human Services has promulgated safe harbor regulations that define practices that are not subject to the anti-kickback statute because such practices would be unlikely to result in fraud or abuse. See 42 C.F.R. § 1001.952. The safe harbors set forth specific conditions that, if met, assure entities involved of not being prosecuted or sanctioned for the arrangement qualifying for the safe harbor. However, safe harbor protection is afforded only to those arrangements that precisely meet all of the conditions set forth in the safe harbor.

The safe harbor for personal services and management contracts, 42 C.F.R. §1001.952(d), is potentially applicable to the Proposed Arrangement. In relevant part for purposes of this advisory opinion, the personal services safe harbor requires that the aggregate compensation paid for the services be set in advance and consistent with fair market value in arm's-length transactions. The Proposed Arrangement would not fit in the safe harbor because the Surgical Group will be paid on a percentage basis, and thus the compensation would not be set in advance. However, the absence of safe harbor protection is not fatal. Instead, the Proposed Arrangement must be subject to case-by-case evaluation.

Like any compensation arrangement between a hospital and a physician who admits or refers patients to such hospital, we are concerned that the Proposed Arrangement could be used to disguise remuneration from the Hospital to reward or induce referrals by the Surgical Group. Specifically, the Proposed Arrangement could encourage the surgeons to admit Federal health care program patients to the Hospital, since the surgeons would receive not only their Medicare Part B professional fee, but also, indirectly, a share of the Hospital's payment, depending on cost savings. In other words, the more procedures a surgeon performs at the Hospital, the more money he or she is likely to receive under the Proposed Arrangement.

While we believe the Proposed Arrangement could result in illegal remuneration if the requisite intent to induce referrals were present, we would not impose sanctions in the particular circumstances presented here and as qualified below.

First, the circumstances and safeguards of the Proposed Arrangement reduce the likelihood that the arrangement will be used to attract referring physicians or to increase referrals from existing physicians. Specifically, participation in the Proposed Arrangement will be limited to surgeons already on the medical staff, thus limiting the likelihood that the Proposed Arrangement will attract other surgeons. In addition, the potential savings derived from procedures for Federal health care program beneficiaries will be capped based on the prior year's admissions of Federal health care program beneficiaries. Finally, the contract term will be limited to one year, reducing any incentive to switch facilities, and admissions will be monitored for changes in severity, age, or payor. Thus, while the incentive to refer will not necessarily be eliminated, it will be substantially reduced.

Second, the structure of the Proposed Arrangement eliminates the risk that the Proposed Arrangement will be used to reward cardiologists or other physicians who refer patients to the Surgical Group or its surgeons. The Surgical Group is the sole participant in the Proposed Arrangement and is composed entirely of cardiac surgeons; no cardiologists or other physicians are members of the Surgical Group or share in its profit distributions. Within the Surgical Group, profits are distributed to its members on a per capita basis, mitigating any incentive for an individual surgeon to generate disproportionate cost savings.

Third, the Proposed Arrangement sets out with specificity the particular actions that will generate the cost savings on which the payments are based. While many of the recommendations in the Practice Patterns Report are simple common sense, they do represent a change in operating room practice, for which the surgeon is responsible and will have liability exposure. While most of the recommendations would appear to present minimal risk, the preparation of the cell saver, blood cross-matching, and product standardization each carry some increased liability risk for the physicians. It is not unreasonable for the surgeon to receive compensation for the increased risk from the proposed change in practice. Moreover, the payments will represent a portion of one year's worth of cost savings and will be limited in amount (i.e., the aggregate cap), duration (i.e., the limited contract term), and scope (i.e., the total savings that can be achieved from the implementation of any one recommendation are limited by appropriate utilization levels). The payments under the Proposed Arrangement do not appear unreasonable, given, among other things, the nature of the actions required of the physicians to implement the twenty-nine recommended actions, the specificity of the payment formula, and the cap on total remuneration to the Surgical Group.[12] We caution that payments of 50% of cost savings in other arrangements, including multi-year arrangements or arrangements with generalized cost savings formulae, could well lead to a different result.

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[12]We are precluded by statute from opining on whether fair market value shall be or was paid for goods, services, or property. See 42 U.S.C. § 1320a-7d(b)(3)(A). While the Requestors have certified that the payments under the Proposed Arrangement are consistent with fair market value, we do not rely on that certification in this opinion, nor have we have made an independent fair market value assessment.

In light of these circumstances and safeguards, the Proposed Arrangement poses a low risk of fraud or abuse under the anti-kickback statute.

III. CONCLUSION

Notwithstanding the foregoing, we reiterate our concerns regarding many arrangements between hospitals and physicians to share cost savings. Improperly designed or implemented arrangements risk adversely affecting patient care and could be vehicles to disguise payments for referrals. For example, an arrangement that cannot be adequately and accurately measured for quality of care would pose a high risk of fraud or abuse, as would one that rewards physicians based on overall cost savings without accountability for specific cost reduction measures. Moreover, arrangements structured so as to pose a heightened potential for patient steering and unfair competition would be considered suspect. In short, this opinion is predicated on the specific arrangement posed by the Requestors and is limited to that specific arrangement. Other apparently similar arrangements could raise different concerns and lead to a different result.

Based on the facts certified in your request for an advisory opinion and supplemental submissions, we conclude: (i) the Proposed Arrangement would constitute an improper payment to induce reduction or limitation of services pursuant to sections 1128A(b)(1)-(2) of the Act, but that the OIG would not impose sanctions under sections 1128A(b)(1)-(2) on the Requestors in connection with the Proposed Arrangement; and (ii) the Proposed Arrangement would potentially generate prohibited remuneration under the anti-kickback statute, if the requisite intent to induce or reward referrals of Federal health care program business were present, but that the OIG would not impose administrative sanctions on the Requestors under sections 1128(b)(7) or 1128A(a)(7) of the Act (as those sections relate to the commission of acts described in section 1128B(b) of the Act) in connection with the Proposed Arrangement.

IV. LIMITATIONS

The limitations applicable to this opinion include the following:

- This advisory opinion is issued only to [names redacted], the requestors of this opinion. This advisory opinion has no application to, and cannot be relied upon by, any other individual or entity.

- This advisory opinion may not be introduced into evidence in any matter involving an entity or individual that is not a requestor to this opinion.

- This advisory opinion is applicable only to the statutory provisions specifically noted above. No opinion is expressed or implied herein with respect to the application of any other Federal, state, or local statute, rule, regulation,

ordinance, or other law that may be applicable to the Proposed Arrangement, including, without limitation, the physician self-referral law, section 1877 of the Act.

- This advisory opinion will not bind or obligate any agency other than the U.S. Department of Health and Human Services.

- This advisory opinion is limited in scope to the specific arrangement described in this letter and has no applicability to other arrangements, even those that appear similar in nature or scope.

- No opinion is expressed herein regarding the liability of any party under the False Claims Act or other legal authorities for any improper billing, claims submission, cost reporting, or related conduct.

This opinion is also subject to any additional limitations set forth at 42 C.F.R. Part 1008.

The OIG will not proceed against the Requestors with respect to any action that is part of the Proposed Arrangement taken in good faith reliance upon this advisory opinion, as long as all of the material facts have been fully, completely, and accurately presented, and the Proposed Arrangement in practice comports with the information provided. The OIG reserves the right to reconsider the questions and issues raised in this advisory opinion and, where the public interest requires, to rescind, modify, or terminate this opinion. In the event that this advisory opinion is modified or terminated, the OIG will not proceed against the Requestors with respect to any action taken in good faith reliance upon this advisory opinion, where all of the relevant facts were fully, completely, and accurately presented, and where such action was promptly discontinued upon notification of the modification or termination of this advisory opinion. An advisory opinion may be rescinded only if the relevant and material facts have not been fully, completely, and accurately disclosed to the OIG.

Sincerely,

/s/

Lewis Morris
Chief Counsel to the Inspector General

[Appendix A Redacted]

[*We redact certain identifying information and certain potentially privileged, confidential, or proprietary information associated with the individual or entity, unless otherwise approved by the requestors.*]

Issued: February 10, 2005

Posted: February 17, 2005

[names and addresses redacted]

Re: OIG Advisory Opinion No. 05-04

Ladies and Gentlemen:

We are writing in response to your request for an advisory opinion concerning a proposed arrangement in which a hospital will share with each of eight cardiology groups a percentage of the hospital's cost savings arising from the cardiology group's implementation of a number of cost reduction measures in certain cardiac catheterization laboratory procedures (the "Proposed Arrangement"). The cost savings will be measured based on the cardiologists' use of specific supplies during designated cardiology procedures. You have inquired whether the Proposed Arrangement would constitute grounds for sanctions arising under: (i) the civil monetary penalty for a hospital's payment to a physician to induce reductions or limitations of services to Medicare or Medicaid beneficiaries under the physician's direct care, sections 1128A(b)(1)-(2) of the Social Security Act (the "Act"); or (ii) the exclusion authority at section 1128(b)(7) of the Act or the civil monetary penalty provision at section 1128A(a)(7) of the Act, as those sections relate to the commission of acts described in section 1128B(b) of the Act, the anti-kickback statute.

You have certified that all of the information provided in your request, including all supplementary letters, is true and correct and constitutes a complete description of the relevant facts and agreements among the parties.

In issuing this opinion, we have relied solely on the facts and information presented to us. We have not undertaken an independent investigation of such information. This opinion is limited to the facts presented. If material facts have not been disclosed or have been misrepresented, this opinion is without force and effect.

Based on the information provided and the totality of the facts as described and certified in your request for an advisory opinion and supplemental submissions, we conclude that: (i) the Proposed Arrangement would constitute an improper payment to induce reduction

or limitation of services pursuant to sections 1128A(b)(1)-(2) of the Act, but that the Office of Inspector General ("OIG") would not impose sanctions on the requestors of this advisory opinion, [names redacted] (collectively, the "Requestors"), in connection with the Proposed Arrangement; and (ii) the Proposed Arrangement would potentially generate prohibited remuneration under the anti-kickback statute, if the requisite intent to induce or reward referrals of Federal health care program business were present, but that the OIG would not impose administrative sanctions on the Requestors under sections 1128(b)(7) or 1128A(a)(7) of the Act (as those sections relate to the commission of acts described in section 1128B(b) of the Act) in connection with the Proposed Arrangement.

This opinion may not be relied on by any persons other than the Requestors and is further qualified as set out in Part IV below and in 42 C.F.R. Part 1008.

I. FACTUAL BACKGROUND

A. Parties

The Hospital. [Name redacted] (the "Hospital") is an acute care hospital in [city and state redacted] that offers a broad range of inpatient and outpatient hospital services, including cardiac catheterization laboratory services. The Hospital is a participating provider in the Medicare and Medicaid programs.

The Cardiology Groups. [Names redacted] (collectively, the "Cardiology Groups," and individually, where applicable, the "Cardiology Group") are four professional associations and one professional corporation that separately employ cardiologists duly licensed in [state redacted] who have active medical staff privileges at the Hospital.[1] The Cardiology Groups refer patients to the Hospital for inpatient and outpatient hospital services. Each Cardiology Group will enter into a separate contract with the Hospital that will set forth the projected savings opportunities applicable to the individual cardiology group.

The Program Administrator. The Hospital has engaged [name redacted] (the "Program Administrator") to administer the Proposed Arrangement. The Program Administrator will collect data and analyze and manage the Proposed Arrangement.[2] The Hospital will pay the Program Administrator a monthly fixed fee certified by the Requestors to be fair market value in an arm's-length transaction for services to be provided by the Program Administrator under the Proposed Arrangement. The fee will not be tied in any way to

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[1]The Cardiology Groups have members who also practice at other hospitals in the region; however, the Hospital is the primary practice location for most of the cardiologists in the Cardiology Groups.

[2]The Program Administrator has developed software products that measure cost, quality, and utilization on a national basis. The products are certified by both the American College of Cardiology and the Society of Thoracic Surgery.

cost savings or the Cardiology Groups' compensation under the Proposed Arrangement.

B. The Proposed Arrangement

Under the Proposed Arrangement, the Hospital will pay each Cardiology Group a share of the first year cost savings directly attributable to specific changes in each Cardiology Group's cardiac catheterization laboratory practices. The majority of the changes involve product standardization for cardiology devices. The Program Administrator conducted a study of the historic practices at the Hospital's cardiac catheterization laboratory and identified seventeen specific cost-savings opportunities. The results of the Program Administrator's study of each Cardiology Group and the specific cost-savings opportunities for each Group are summarized in a "Practice Patterns Report."[3] The Hospital and each Cardiology Group have reviewed the Practice Patterns Report for medical appropriateness and each has adopted its recommendations and conclusions.

In general, the Practice Patterns Report recommends that the Cardiology Groups change current cardiac catheterization laboratory practices to curb inappropriate use or waste of medical supplies. The seventeen recommendations can be grouped into three categories.

The first category, involving twelve recommendations, consists of product standardization of certain cardiology devices where medically appropriate. The Practice Patterns Report recommends that each Cardiology Group standardize the types of cardiac catheterization devices (stents, balloons, interventional guidewires and catheters, vascular closure, diagnostic devices, pacemakers, and defibrillators) used by the Cardiology Group.[4] Each Cardiology Group would be required to work in conjunction with the Hospital to evaluate and clinically review vendors and products. Each Cardiology Group would agree to use the selected products, where medically appropriate, which may require additional training or changes in clinical practice.

The second category, involving three recommendations, consists of limiting the use of certain vascular closure devices to an "as needed" basis for inpatient coronary interventional procedures and diagnostic procedures. The Requestors have certified that the vascular closure devices will be readily available, albeit unopened, in the procedure room. The Requestors have certified that the reduction in use of vascular closure devices will not adversely affect patient care.

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[3]The Practice Patterns Report for the Cardiology Groups, dated October 2004, is attached to this advisory opinion as Appendix A. The Requestors' original submission included additional cost savings recommendations that posed an unacceptable risk of fraud and abuse. The Requestors withdrew those recommendations from the Proposed Arrangement.

[4]We note that the Practice Patterns Report identifies with specificity the vendors and products at issue.

The final category, involving contrast agents, consists of two recommendations to substitute, in whole or in part, less costly items for the items currently being used by the physicians (hereafter, the "products substitution" recommendations).

The Proposed Arrangement contains several safeguards intended to protect against inappropriate reductions in services. With respect to the "as needed" use of vascular closure devices and the products substitution recommendations, the Proposed Arrangement would utilize objective historical and clinical measures reasonably related to the practices and the patient population at the Hospital and in some cases national averages to establish a "floor" beyond which no savings would accrue to any Cardiology Group.

For example, according to the Requestors, the national average for utilization of vascular closure devices for stent patients is 15.5%. Vascular closure devices are currently utilized at the Hospital on 30% of the cases specified under the Proposed Arrangement. Based upon this information, the Program Administrator has set the floor for this recommendation at 20% of stent patients. Cardiology Groups will receive no share of any savings resulting from the reduction of use of vascular closure devices beyond the 20% floor.

For the proposed product substitution recommendations, the Program Administrator has identified national averages and historic patterns of use at the Hospital or at hospitals with comparable practices and patient populations and has established quality thresholds beyond which no cost savings will be credited. For example, the Practice Patterns Report indicates that certain less expensive contrast agents could be used in 95% of the cases without an adverse impact on patient care.[5] Accordingly, any savings from using a less expensive contrast agent in more than 95% of the cases will not be credited to the Cardiology Groups.

Importantly, with respect to the product standardization of cardiology devices, the Requestors have certified that the individual cardiologists will make a patient-by-patient determination of the most appropriate device and the availability of the full range of devices will not be compromised by the product standardization. The Requestors have further certified that individual physicians will still have available the same selection of devices after implementation of the Proposed Arrangement as before and that the economies gained through the Proposed Arrangement will result from inherent clinical and fiscal value and not from restricting the availability of devices.

According to the Program Administrator, if implemented in accordance with the Practice Patterns Report's specifications, the seventeen recommendations would present substantial cost savings opportunities for the Hospital without adversely impacting the quality of patient care.

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[5]We note that the Practice Patterns Report identifies with specificity the product subsitutions at issue.

The Hospital will enter into a separate contract with each Cardiology Group that will specify the historic costs, base year costs, and projected cost-savings opportunities applicable to the group resulting from implementation of the seventeen recommendations in the Practice Patterns Report. Under each contract, the Hospital will pay the contracting Cardiology Group 50% of the cost savings for a period of one year. At the end of the year, cost savings will be calculated separately for each of the seventeen recommendations for each Group; this will preclude shifting of cost savings and ensure that savings generated by utilization beyond the set targets, as applicable, will not be credited to each Cardiology Group. This payment will constitute the entire compensation paid to each Cardiology Group for services performed under the individual contracts memorializing the Proposed Arrangement. The payment to each Cardiology Group will be calculated using the same formula. For purposes of calculating the payment to each Cardiology Group, the actual costs incurred for the items specified in the seventeen recommendations when used by cardiologists in the Cardiology Group during the specified procedures (the "current year costs"[6]) will be subtracted from the historic costs for the same items when used during comparable procedures in the base year (the "base year costs"[7]). The current year costs will be adjusted to account for any inappropriate reductions in use of items beyond the targets set in the Practice Patterns Report. The payment to each Cardiology Group will be 50% of the difference between its adjusted current year costs and base year costs, if any.

The Hospital will make an aggregate payment to each Cardiology Group, all of which distribute profits to their members on a per capita basis. Payments to each Cardiology Group will also be subject to the following limitations:

- If the volume of procedures payable by a Federal health care program in the current year exceeds the volume of like procedures payable by a Federal health care program performed in the base year, there will be no sharing of cost savings for the additional procedures.

- To minimize the cardiologists' financial incentive to steer more costly patients to other hospitals, the case severity, ages, and payors of the patient population treated under the Proposed Arrangement will be monitored by a committee composed of representatives of the Requestors, using generally-accepted standards. If there are significant changes from historical

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[6]The current year will be the twelve-month term of the contract for which each of the Cardiology Groups will be compensated under the Proposed Arrangement.

[7]The "base year" will be the twelve months preceding the effective date of the contract. For purposes of this opinion, the Proposed Arrangement is limited to the one-year term of the contract; accordingly, this opinion is without force and effect with respect to any future renewal or extension of the Proposed Arrangement. Notwithstanding, we note that any renewal or extension of the Proposed Arrangement should incorporate updated base year costs.

measures, the cardiologist at issue will be terminated from participation in the Proposed Arrangement.

- The aggregate payment to each Cardiology Group will not exceed 50% of the projected cost savings identified in the Practice Patterns Report.

The Hospital and the Cardiology Groups will document the activities and the payment methodology under the Proposed Arrangement and will make the documentation available to the Secretary of the United States Department of Health and Human Services, upon request. In addition, the Hospital and the Cardiology Groups will disclose the Proposed Arrangement to the patient, including the fact that the Cardiology Groups' compensation is based on a percentage of the Hospital's cost savings. The disclosure will be made to the patient before the patient is admitted to the Hospital for a procedure covered by the Proposed Arrangement; if pre-admission disclosure is impracticable (e.g., the patient is admitted for an unscheduled procedure or the need for the procedure is determined after admission), the disclosure will be made before the patient consents to the procedure. The disclosures will be in writing, and patients will have an opportunity, if desired, to review details of the Proposed Arrangement, including the specific cost savings measures applicable to the patient's procedure.

II. LEGAL ANALYSIS

Arrangements like the Proposed Arrangement are designed to align incentives by offering physicians a portion of a hospital's cost savings in exchange for implementing cost saving strategies. Under the current reimbursement system, the burden of these costs falls on hospitals, not physicians. Payments to physicians based on cost savings may be intended to motivate them to reduce hospital costs associated with procedures performed by physicians at the hospitals.

Properly structured, arrangements that share cost savings can serve legitimate business and medical purposes. Specifically, properly structured arrangements may increase efficiency and reduce waste, thereby potentially increasing a hospital's profitability. However, such arrangements can potentially influence physician judgment to the detriment of patient care. Our concerns include, but are not limited to, the following: (i) stinting on patient care; (ii) "cherry picking" healthy patients and steering sicker (and more costly) patients to hospitals that do not offer such arrangements; (iii) payments in exchange for patient referrals; and (iv) unfair competition (a "race to the bottom") among hospitals offering cost savings programs to foster physician loyalty and to attract more referrals.

Hospital cost savings programs in general, and the Proposed Arrangement in particular, may implicate at least three Federal legal authorities: (i) the civil monetary penalty for reductions or limitations of direct patient care services provided to Federal health care program beneficiaries, sections 1128A(b)(1)-(2) of the Act; (ii) the anti-kickback statute, section 1128B(b) of the Act; and (iii) the physician self-referral law, section 1877 of the

Act.[8] We address the first two of these authorities; section 1877 of the Act falls outside the scope of the OIG's advisory opinion authority. We express no opinion on the application of section 1877 of the Act to the Proposed Arrangement.

A. The Civil Monetary Penalty, Sections 1128A(b)(1)-(2) of the Act

Sections 1128A(b)(1)-(2) of the Act establish a civil monetary penalty ("CMP") against any hospital or critical access hospital that knowingly makes a payment directly or indirectly to a physician (and any physician that receives such a payment) as an inducement to reduce or limit items or services to Medicare or Medicaid beneficiaries under the physician's direct care. Hospitals that make (and physicians that receive) such payments are liable for CMPs of up to $2,000 per patient covered by the payments. See id. There is no requirement that the prohibited payment be tied to a specific patient or to a reduction in medically necessary care. The CMP applies only to reductions or limitations of items or services provided to Medicare and Medicaid fee-for-service beneficiaries.[9]

The CMP prohibits payments by hospitals to physicians that may induce physicians to reduce or limit items or services furnished to their Medicare and Medicaid patients. A threshold inquiry is whether the Proposed Arrangement will induce physicians to reduce or limit items or services. Given the specificity of the Proposed Arrangement, it is possible to review the proposed opportunities for savings individually and evaluate their potential impact on patient care.

Having reviewed the seventeen recommendations, we conclude that all of the recommendations implicate the CMP. Simply put, the recommendations under the Proposed Arrangement regarding standardization of devices, limitations on the use of vascular closure devices, and products substitution constitute an inducement to reduce or limit the current medical practice at the Hospital. Thus, we find that the CMP would

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[8]In addition, nonprofit hospital arrangements raise issues of private inurement and private benefit under the Internal Revenue Service's income tax regulations in connection with section 501(c)(3) of the Internal Revenue Code. See Rev. Rul. 69-383, 1969-2 C.B. 113. We express no opinion on the application of the Internal Revenue Code to the Proposed Arrangement.

[9]Physician incentive arrangements related to Medicare risk-based managed care contracts, similar Medicaid contracts, and Medicare Advantage plans (formerly Medicare + Choice) are subject to regulation by the Secretary pursuant to sections 1876(i)(8), 1903(m)(2)(A)(x), and 1852(j)(4) of the Act (respectively), in lieu of being subject to sections 1128A(b)(1)-(2). See OIG letter regarding hospital-physician incentive plans for Medicare and Medicaid beneficiaries enrolled in managed care plans (dated August 19, 1999), available at http://oig.hhs.gov/fraud/docs/alertsandbulletins/gsletter.htm. See also 42 C.F.R. § 417.479 (Medicare HMOs or competitive medical plans); 42 C.F.R. § 422.208 (Medicare Advantage plans); 42 C.F.R. § 438.6 (Medicaid risk plans).

apply to the Proposed Arrangement. We recognize that the current medical practice may involve care that exceeds the requirements of medical necessity. However, whether the current medical practice reflects necessity or prudence is irrelevant for purposes of the CMP.

Notwithstanding, the Proposed Arrangement has several features that, in combination, provide sufficient safeguards so that we would not seek sanctions against the Requestors under sections 1128A(b)(1)-(2) of the Act.

First, the specific cost-saving actions and resulting savings are clearly and separately identified. The transparency of the Proposed Arrangement will allow for public scrutiny and individual physician accountability for any adverse effects of the Proposed Arrangement, including any difference in treatment among patients based on nonclinical indicators. The transparency of the incentives for specific actions and specific procedures will also facilitate accountability through the medical-legal professional liability system.

Second, the Requestors have proffered credible medical support for the position that implementation of the recommendations will not adversely affect patient care. The Proposed Arrangement will be periodically reviewed by the Requestors to confirm that the Proposed Arrangement is not having an adverse impact on clinical care.[10]

Third, the payments under the Proposed Arrangement are based on all procedures performed, regardless of the patients' insurance coverage, subject to the cap on payment for Federal health care program procedures. Moreover, the procedures to which the Proposed Arrangement applies are not disproportionately performed on Federal health care program beneficiaries. Additionally, the cost savings are calculated on the Hospital's actual out-of-pocket acquisition costs, not an accounting convention.

Fourth, the Proposed Arrangement protects against inappropriate reductions in services by utilizing objective historical and clinical measures to establish baseline thresholds beyond which no savings accrue to the Cardiology Groups. The Requestors have certified that these baseline measures are reasonably related to the Hospital's or comparable hospitals' practices and patient populations. These safeguards are action-specific and not simply based on isolated patient outcome data unrelated to the specific changes in catheterization laboratory practices.

Fifth, the product standardization portion of the Proposed Arrangement further protects

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[10]We have had the Proposed Arrangement reviewed by an independent medical expert, as well as a government medical expert, who both concluded that the proposed cost savings measures, as described in the advisory opinion request and supplemental submissions, should not adversely affect patient care. For purposes of this opinion, however, we rely solely on the Requestors' certifications and nothing in this advisory opinion should be construed as an endorsement or conclusion as to the medical propriety of the specific activities being undertaken as part of the Proposed Arrangement.

against inappropriate reductions in services by ensuring that individual physicians will still have available the same selection of devices after implementation of the Proposed Arrangement as before. The Proposed Arrangement is designed to produce savings through inherent clinical and fiscal value and not from restricting the availability of devices.

Sixth, the Hospital and the Cardiology Groups will provide written disclosures of their involvement in the Proposed Arrangement to patients whose care may be affected by the Proposed Arrangement and will provide patients an opportunity to review the cost savings recommendations prior to admission to the Hospital (or, where pre-admission consent is impracticable, prior to consenting to the procedure). While we do not believe that, standing alone, such disclosures offer sufficient protection from program or patient abuse, effective and meaningful disclosure offers some protection against possible abuses of patient trust.[11]

Seventh, the financial incentives under the Proposed Arrangement are reasonably limited in duration and amount.

Eighth, because each Cardiology Group's profits are distributed to its members on a per capita basis, any incentive for an individual cardiologist to generate disproportionate cost savings is mitigated.

Our decision not to impose sanctions on the Requestors in connection with the Proposed Arrangement is an exercise of our discretion and is consistent with our Special Advisory Bulletin on "Gainsharing Arrangements and CMPs for Hospital Payments to Physicians to Reduce or Limit Services to Beneficiaries" (July 1999) (the "Special Advisory Bulletin"). We reiterate that the CMP applies to any payment by a hospital to a physician that is intended to induce the reduction or limitation of items or services to Medicare or Medicaid patients under the physician's direct clinical care. The Proposed Arrangement is markedly different from many "gainsharing" plans, particularly those that purport to pay physicians a percentage of generalized cost savings not tied to specific, identifiable cost-lowering activities. Importantly, the Proposed Arrangement sets out the specific actions to be taken and ties the remuneration to the actual, verifiable cost savings attributable to those actions. This transparency allows an assessment of the likely effect of the Proposed Arrangement on quality of care and ensures that the identified actions will be the cause of any savings.

By contrast, many gainsharing plans contain features that heighten the risk that payments will lead to inappropriate reductions or limitations of services. These features include,

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[11]Ordinarily, we would expect patient disclosures to be coupled with patient satisfaction surveys that closely monitor patient perceptions of their care. However, in the context of the Proposed Arrangement, which focuses on items used in the catheterization laboratory, we believe that patient satisfaction surveys would not be effective.

but are not limited to, the following:

- There is no demonstrable direct connection between individual actions and any reduction in the hospital's out-of-pocket costs (and any corresponding "gainsharing" payment).

- The individual actions that would give rise to the savings are not identified with specificity.

- There are insufficient safeguards against the risk that other, unidentified actions, such as premature hospital discharges, might actually account for any "savings."

- The quality of care indicators are of questionable validity and statistical significance.

- There is no independent verification of cost savings, quality of care indicators, or other essential aspects of the arrangement.

Simply put, many "gainsharing" plans present substantial risks for both patient and program abuse – risks that are not present in the Proposed Arrangement. Given the limited duration and scope of the Proposed Arrangement, the safeguards provide sufficient protections against patient and program abuse. Other arrangements, including those that are longer in duration or more expansive in scope than the Proposed Arrangement, are likely to require additional or different safeguards.

B. The Anti-Kickback Statute

The anti-kickback statute makes it a criminal offense knowingly and willfully to offer, pay, solicit, or receive any remuneration to induce or reward referrals of items or services reimbursable by a Federal health care program. See section 1128B(b) of the Act. Where remuneration is paid purposefully to induce or reward referrals of items or services payable by a Federal health care program, the anti-kickback statute is violated. By its terms, the statute ascribes criminal liability to parties on both sides of an impermissible "kickback" transaction. For purposes of the anti-kickback statute, "remuneration" includes the transfer of anything of value, directly or indirectly, overtly or covertly, in cash or in kind.

The statute has been interpreted to cover any arrangement where one purpose of the remuneration was to obtain money for the referral of services or to induce further referrals. United States v. Kats, 871 F.2d 105 (9th Cir. 1989); United States v. Greber, 760 F.2d 68 (3d Cir.), cert. denied, 474 U.S. 988 (1985). Violation of the statute constitutes a felony punishable by a maximum fine of $25,000, imprisonment up to five years, or both. Conviction will also lead to automatic exclusion from Federal health care programs, including Medicare and Medicaid. Where a party commits an act described in section 1128B(b) of the Act, the OIG may initiate administrative proceedings to impose

civil monetary penalties on such party under section 1128A(a)(7) of the Act. The OIG may also initiate administrative proceedings to exclude such party from the Federal health care programs under section 1128(b)(7) of the Act.

The Department of Health and Human Services has promulgated safe harbor regulations that define practices that are not subject to the anti-kickback statute because such practices would be unlikely to result in fraud or abuse. See 42 C.F.R. § 1001.952. The safe harbors set forth specific conditions that, if met, assure entities involved of not being prosecuted or sanctioned for the arrangement qualifying for the safe harbor. However, safe harbor protection is afforded only to those arrangements that precisely meet all of the conditions set forth in the safe harbor.

The safe harbor for personal services and management contracts, 42 C.F.R. §1001.952(d), is potentially applicable to the Proposed Arrangement. In relevant part for purposes of this advisory opinion, the personal services safe harbor requires that the aggregate compensation paid for the services be set in advance and consistent with fair market value in arm's-length transactions. The Proposed Arrangement would not fit in the safe harbor because the Cardiology Groups will be paid on a percentage basis, and thus the compensation would not be set in advance. However, the absence of safe harbor protection is not fatal. Instead, the Proposed Arrangement must be subject to case-by-case evaluation.

Like any compensation arrangement between a hospital and a physician who admits or refers patients to such hospital, we are concerned that the Proposed Arrangement could be used to disguise remuneration from the Hospital to reward or induce referrals by the Cardiology Groups. Specifically, the Proposed Arrangement could encourage the cardiologists to admit Federal health care program patients to the Hospital, since the cardiologists would receive not only their Medicare Part B professional fee, but also, indirectly, a share of the Hospital's payment, depending on cost savings. In other words, the more procedures a cardiologist performs at the Hospital, the more money he or she is likely to receive under the Proposed Arrangement.

While we believe the Proposed Arrangement could result in illegal remuneration if the requisite intent to induce referrals were present, we would not impose sanctions in the particular circumstances presented here and as qualified below.

First, the circumstances and safeguards of the Proposed Arrangement reduce the likelihood that the arrangement will be used to attract referring physicians or to increase referrals from existing physicians. Specifically, participation in the Proposed Arrangement will be limited to cardiologists already on the medical staff, thus limiting the likelihood that the Proposed Arrangement will attract other cardiologists. In addition, the potential savings derived from procedures for Federal health care program beneficiaries will be capped based on the prior year's admissions of Federal health care program beneficiaries. Finally, the contract term will be limited to one year, reducing any incentive to switch facilities, and admissions will be monitored for changes in severity, age, or payor. Thus, while the incentive to refer will not necessarily be eliminated, it will

be substantially reduced.

Second, the structure of the Proposed Arrangement eliminates the risk that the Proposed Arrangement will be used to reward surgeons or other physicians who refer patients to the Cardiology Groups or their cardiologists. The Cardiology Groups are the sole participants in the Proposed Arrangement and are composed entirely of cardiologists; no surgeons or other physicians are members of the Cardiology Groups or share in its profit distributions. Within the Cardiology Groups, profits are distributed to their members on a per capita basis, mitigating any incentive for an individual cardiologist to generate disproportionate cost savings.

Third, the Proposed Arrangement sets out with specificity the particular actions that will generate the cost savings on which the payments are based. The recommendations in the Practice Patterns Report represent a change in cardiac catheterization laboratory procedure, for which the cardiologists are responsible and will have liability exposure. The products standardization, limitation on vascular closure devices, and product substitutions carry some increased liability risk for the physicians. It is not unreasonable for the cardiologists to receive compensation for the increased risk from the proposed change in practice. Moreover, the payments will represent a portion of one year's worth of cost savings and will be limited in amount (i.e., the aggregate cap), duration (i.e., the limited contract term), and scope (i.e., the total savings that can be achieved from the implementation of any one recommendation are limited by appropriate utilization levels). The payments under the Proposed Arrangement do not appear unreasonable, given, among other things, the nature of the actions required of the physicians to implement the seventeen recommended actions, the specificity of the payment formula, and the cap on total remuneration to each of the Cardiology Groups.[12] We caution that payments of 50% of cost savings in other arrangements, including multi-year arrangements or arrangements with generalized cost savings formulae, could well lead to a different result.

In light of these circumstances and safeguards, the Proposed Arrangement poses a low risk of fraud or abuse under the anti-kickback statute.

III. CONCLUSION

Notwithstanding the foregoing, we reiterate our concerns regarding many arrangements between hospitals and physicians to share cost savings. Improperly designed or implemented arrangements risk adversely affecting patient care and could be vehicles to disguise payments for referrals. For example, an arrangement that cannot be adequately and accurately measured for quality of care would pose a high risk of fraud or abuse, as

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[12]We are precluded by statute from opining on whether fair market value shall be or was paid for goods, services, or property. See 42 U.S.C. § 1320a-7d(b)(3)(A). While the Requestors have certified that the payments under the Proposed Arrangement are consistent with fair market value, we do not rely on that certification in this opinion, nor have we have made an independent fair market value assessment.

would one that rewards physicians based on overall cost savings without accountability for specific cost reduction measures. Moreover, arrangements structured so as to pose a heightened potential for patient steering and unfair competition would be considered suspect. In short, this opinion is predicated on the specific arrangement posed by the Requestors and is limited to that specific arrangement. Other apparently similar arrangements could raise different concerns and lead to a different result.

Based on the facts certified in your request for an advisory opinion and supplemental submissions, we conclude: (i) the Proposed Arrangement would constitute an improper payment to induce reduction or limitation of services pursuant to sections 1128A(b)(1)-(2) of the Act, but that the OIG would not impose sanctions under sections 1128A(b)(1)-(2) on the Requestors in connection with the Proposed Arrangement; and (ii) the Proposed Arrangement would potentially generate prohibited remuneration under the anti-kickback statute, if the requisite intent to induce or reward referrals of Federal health care program business were present, but that the OIG would not impose administrative sanctions on the Requestors under sections 1128(b)(7) or 1128A(a)(7) of the Act (as those sections relate to the commission of acts described in section 1128B(b) of the Act) in connection with the Proposed Arrangement.

IV. LIMITATIONS

The limitations applicable to this opinion include the following:

- This advisory opinion is issued only to [names redacted], the requestors of this opinion. This advisory opinion has no application to, and cannot be relied upon by, any other individual or entity.

- This advisory opinion may not be introduced into evidence in any matter involving an entity or individual that is not a requestor to this opinion.

- This advisory opinion is applicable only to the statutory provisions specifically noted above. No opinion is expressed or implied herein with respect to the application of any other Federal, state, or local statute, rule, regulation, ordinance, or other law that may be applicable to the Proposed Arrangement, including, without limitation, the physician self-referral law, section 1877 of the Act.

- This advisory opinion will not bind or obligate any agency other than the U.S. Department of Health and Human Services.

- This advisory opinion is limited in scope to the specific arrangement described in this letter and has no applicability to other arrangements, even those that appear similar in nature or scope.

- No opinion is expressed herein regarding the liability of any party under the

False Claims Act or other legal authorities for any improper billing, claims submission, cost reporting, or related conduct.

This opinion is also subject to any additional limitations set forth at 42 C.F.R. Part 1008.

The OIG will not proceed against the Requestors with respect to any action that is part of the Proposed Arrangement taken in good faith reliance upon this advisory opinion, as long as all of the material facts have been fully, completely, and accurately presented, and the Proposed Arrangement in practice comports with the information provided. The OIG reserves the right to reconsider the questions and issues raised in this advisory opinion and, where the public interest requires, rescind, modify, or terminate this opinion. In the event that this advisory opinion is modified or terminated, the OIG will not proceed against the Requestors with respect to any action taken in good faith reliance upon this advisory opinion, where all of the relevant facts were fully, completely, and accurately presented, and where such action was promptly discontinued upon notification of the modification or termination of this advisory opinion. An advisory opinion may be rescinded only if the relevant and material facts have not been fully, completely, and accurately disclosed to the OIG.

Sincerely,

/s/

Lewis Morris
Chief Counsel to the Inspector General

[Appendix A Redacted]

[*We redact certain identifying information and certain potentially privileged, confidential, or proprietary information associated with the individual or entity, unless otherwise approved by the requestors.*]

Issued: February 18, 2005

Posted: February 25, 2005

[names and addresses redacted]

Re: **OIG Advisory Opinion No. 05-05**

Ladies and Gentlemen:

We are writing in response to your request for an advisory opinion concerning a proposed arrangement in which a hospital will share with a group of cardiologists a percentage of the hospital's cost savings arising from the cardiologists' implementation of a number of cost reduction measures in certain procedures (the "Proposed Arrangement"). The cost savings will be measured based on the cardiologists' use of specific supplies during designated cardiac catheterization laboratory procedures. You have inquired whether the Proposed Arrangement would constitute grounds for sanctions arising under: (i) the civil monetary penalty for a hospital's payment to a physician to induce reductions or limitations of services to Medicare or Medicaid beneficiaries under the physician's direct care, sections 1128A(b)(1)-(2) of the Social Security Act (the "Act"); or (ii) the exclusion authority at section 1128(b)(7) of the Act or the civil monetary penalty provision at section 1128A(a)(7) of the Act, as those sections relate to the commission of acts described in section 1128B(b) of the Act, the anti-kickback statute.

You have certified that all of the information provided in your request, including all supplementary letters, is true and correct and constitutes a complete description of the relevant facts and agreements among the parties.

In issuing this opinion, we have relied solely on the facts and information presented to us. We have not undertaken an independent investigation of such information. This opinion is limited to the facts presented. If material facts have not been disclosed or have been misrepresented, this opinion is without force and effect.

Based on the information provided and the totality of the facts as described and certified in your request for an advisory opinion and supplemental submissions, we conclude that: (i) the Proposed Arrangement would constitute an improper payment to induce reduction or limitation of services pursuant to sections 1128A(b)(1)-(2) of the Act, but that the

Office of Inspector General ("OIG") would not impose sanctions on the requestors of this advisory opinion, [names redacted] (the "Requestors"), in connection with the Proposed Arrangement; and (ii) the Proposed Arrangement would potentially generate prohibited remuneration under the anti-kickback statute, if the requisite intent to induce or reward referrals of Federal health care program business were present, but that the OIG would not impose administrative sanctions on the Requestors under sections 1128(b)(7) or 1128A(a)(7) of the Act (as those sections relate to the commission of acts described in section 1128B(b) of the Act) in connection with the Proposed Arrangement.

This opinion may not be relied on by any persons other than the Requestors and is further qualified as set out in Part IV below and in 42 C.F.R. Part 1008.

I. FACTUAL BACKGROUND

A. Parties

The Hospital. [Name redacted] (the "Hospital") is an acute care hospital in [city and state redacted] that offers a broad range of inpatient and outpatient hospital services, including cardiac catheterization laboratory services. The Hospital is a participating provider in the Medicare and Medicaid programs.

The Cardiology Group. [Name redacted] (the "Cardiology Group") is a professional association that employs physicians who are duly licensed in [state redacted] and have active medical staff privileges at the Hospital.[1] The Cardiology Group refers patients to the Hospital for inpatient and outpatient hospital services.

The Program Administrator. The Hospital has engaged [name redacted] (the "Program Administrator") to administer the Proposed Arrangement. The Program Administrator will collect data and analyze and manage the Proposed Arrangement.[2] The Hospital will pay the Program Administrator a fixed fee certified by the Requestors to be fair market value in an arm's-length transaction for services to be provided by the Program Administrator under the Proposed Arrangement. The fee will not be tied in any way to cost savings or the Cardiology Group's compensation under the Proposed Arrangement.

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[1]The Cardiology Group has members who also practice at other hospitals in the region; however, the Hospital is the primary practice location for most of the cardiologists in the Cardiology Group.

[2]The Program Administrator has developed software products that measure cost, quality, and utilization on a national basis. The products are certified by both the American College of Cardiology and the Society of Thoracic Surgery.

B. The Proposed Arrangement

Under the Proposed Arrangement, the Hospital will pay the Cardiology Group a share of the first year cost savings directly attributable to specific changes in the Cardiology Group's cardiac catheterization laboratory practices. The Program Administrator conducted a study of the historic practices at the Hospital's cardiac catheterization laboratory and identified twelve specific cost-savings opportunities. The results of the Program Administrator's study of the Cardiology Group and the specific cost-savings opportunities are summarized in a "Practice Patterns Report."[3] The Hospital and the Cardiology Group have reviewed the Practice Patterns Report for medical appropriateness and each has adopted its recommendations and conclusions.

In general, the Practice Patterns Report recommends that the Cardiology Group change current cardiac catheterization laboratory practices to curb inappropriate use or waste of medical supplies. The twelve recommendations can be grouped into two categories.

The first category, involving ten recommendations, consists of product standardization where medically appropriate. The Practice Patterns Report recommends that the Cardiology Group standardize the types of cardiac catheterization devices (stents, balloons, interventional guidewires and catheters, vascular closure devices, diagnostic devices, pacemakers, and defibrillators) used by the Cardiology Group.[4] The Cardiology Group would be required to work in conjunction with the Hospital to evaluate and clinically review vendors and products. The Cardiology Group would agree to use the selected products, where medically appropriate, which may require additional training or changes in clinical practice.

The second category, involving two recommendations, consists of limiting the use of certain vascular closure devices to an "as needed" basis for inpatient coronary interventional procedures and diagnostic procedures. The Requestors have certified that the vascular closure devices will be readily available, albeit unopened, in the procedure room. The Requestors have certified that the reduction in use of vascular closure devices will not adversely affect patient care.

The Proposed Arrangement contains several safeguards intended to protect against inappropriate reductions in services. Importantly, with respect to the product standardization recommendation, the Requestors have certified that the individual

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[3]The Practice Patterns Report for the Cardiology Group, dated October 2004, is attached to this advisory opinion as Appendix A. The Requestors' original submission included additional cost savings recommendations that posed an unacceptable risk of fraud and abuse. The Requestors withdrew those recommendations from the Proposed Arrangement.

[4]We note that the Practice Patterns Report identifies with specificity the vendors and products at issue.

cardiologists will make a patient-by-patient determination of the most appropriate device and the availability of the full range of devices will not be compromised by the product standardization. The Requestors have further certified that individual physicians will still have available the same selection of devices after implementation of the Proposed Arrangement as before and that the economies gained through the Proposed Arrangement will result from inherent clinical and fiscal value and not from restricting the availability of devices.

With respect to the limitation on use of vascular closure devices, the Proposed Arrangement would utilize objective historical and clinical measures reasonably related to the practices and the patient population at the Hospital to establish a "floor" beyond which no savings would accrue to the Cardiology Group. For example, according to the Requestors, vascular closure devices for femoral access cases are currently utilized at the Hospital on 26.1% of the cases specified under the Proposed Arrangement. The Program Administrator has determined through analysis of national data that it is reasonable to reduce the use of vascular closure devices on these cases to 15% of patients and that this reduction would not adversely impact patient care. Thus, the Cardiology Group will receive no share of any savings resulting from the reduction of use of vascular closure devices beyond the 15% floor.

According to the Program Administrator, if implemented in accordance with the Practice Patterns Report's specifications, the twelve recommendations would present substantial cost savings opportunities for the Hospital without adversely impacting the quality of patient care.

The Hospital will pay the Cardiology Group 50% of the cost savings achieved by implementing the twelve recommendations in the Practice Patterns Report for a period of one year. At the end of the year, cost savings will be calculated separately for each of the twelve recommendations; this will preclude shifting of cost savings and ensure that savings generated by utilization beyond the set targets, as applicable, will not be credited to the Cardiology Group. This payment will constitute the entire compensation paid to the Cardiology Group for services performed under the contract memorializing the Proposed Arrangement between the Cardiology Group and the Hospital. For purposes of calculating the payment to the Cardiology Group, the cost savings will be calculated by subtracting the actual costs incurred for the items specified in the twelve recommendations when used by cardiologists in the Cardiology Group during the specified procedures (the "current year costs"[5]) from the historic costs for the same items

[5]The current year will be the twelve-month term of the contract for which the Cardiology Group will be compensated under the Proposed Arrangement.

when used during comparable procedures in the base year (the "base year costs"[6]). The current year costs will be adjusted to account for any inappropriate reductions in use of items beyond the targets set in the Practice Patterns Report. The payment to the Cardiology Group will be 50% of the difference between the adjusted current year costs and base year costs, if any.

The Hospital will make an aggregate payment to the Cardiology Group, which distributes its profits to each of its members on a per capita basis. Payments to the Cardiology Group will also be subject to the following limitations:

- If the volume of procedures payable by a Federal health care program in the current year exceeds the volume of like procedures payable by a Federal health care program performed in the base year, there will be no sharing of cost savings for the additional procedures.

- To minimize the cardiologists' financial incentive to steer more costly patients to other hospitals, the case severity, ages, and payors of the patient population treated under the Proposed Arrangement will be monitored by a committee composed of representatives of the Requestors, using generally-accepted standards. If there are significant changes from historical measures, the cardiologist at issue will be terminated from participation in the Proposed Arrangement.

- The aggregate payment to the Cardiology Group will not exceed 50% of the projected cost savings identified in the Practice Patterns Report.

The Hospital and the Cardiology Group will document the activities and the payment methodology under the Proposed Arrangement and will make the documentation available to the Secretary of the United States Department of Health and Human Services, upon request. In addition, the Hospital and the Cardiology Group will disclose the Proposed Arrangement to the patient, including the fact that the Cardiology Group's compensation is based on a percentage of the Hospital's cost savings. The disclosure will be made to the patient before the patient is admitted to the Hospital for a procedure covered by the Proposed Arrangement; if pre-admission disclosure is impracticable (e.g., the patient is admitted for an unscheduled procedure or the need for the procedure is determined after admission), the disclosure will be made before the patient consents to the procedure. The disclosures will be in writing, and patients will have an opportunity, if desired, to review details of the Proposed Arrangement, including the specific cost

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[6]The "base year" will be the twelve months preceding the effective date of the contract. For purposes of this opinion, the Proposed Arrangement is limited to the one-year term of the contract; accordingly, this opinion is without force and effect with respect to any future renewal or extension of the Proposed Arrangement. Notwithstanding, we note that any renewal or extension of the Proposed Arrangement should incorporate updated base year costs.

savings measures applicable to the patient's procedure.

II. LEGAL ANALYSIS

Arrangements like the Proposed Arrangement are designed to align incentives by offering physicians a portion of a hospital's cost savings in exchange for implementing cost saving strategies. Under the current reimbursement system, the burden of these costs falls on hospitals, not physicians. Payments to physicians based on cost savings may be intended to motivate them to reduce hospital costs associated with procedures performed by physicians at the hospitals.

Properly structured, arrangements that share cost savings can serve legitimate business and medical purposes. Specifically, properly structured arrangements may increase efficiency and reduce waste, thereby potentially increasing a hospital's profitability. However, such arrangements can potentially influence physician judgment to the detriment of patient care. Our concerns include, but are not limited to, the following: (i) stinting on patient care; (ii) "cherry picking" healthy patients and steering sicker (and more costly) patients to hospitals that do not offer such arrangements; (iii) payments in exchange for patient referrals; and (iv) unfair competition (a "race to the bottom") among hospitals offering cost savings programs to foster physician loyalty and to attract more referrals.

Hospital cost savings programs in general, and the Proposed Arrangement in particular, may implicate at least three Federal legal authorities: (i) the civil monetary penalty for reductions or limitations of direct patient care services provided to Federal health care program beneficiaries, sections 1128A(b)(1)-(2) of the Act; (ii) the anti-kickback statute, section 1128B(b) of the Act; and (iii) the physician self-referral law, section 1877 of the Act.[7] We address the first two of these authorities; section 1877 of the Act falls outside the scope of the OIG's advisory opinion authority. We express no opinion on the application of section 1877 of the Act to the Proposed Arrangement.

A. The Civil Monetary Penalty, Sections 1128A(b)(1)-(2) of the Act

Sections 1128A(b)(1)-(2) of the Act establish a civil monetary penalty ("CMP") against any hospital or critical access hospital that knowingly makes a payment directly or indirectly to a physician (and any physician that receives such a payment) as an inducement to reduce or limit items or services to Medicare or Medicaid beneficiaries under the physician's direct care. Hospitals that make (and physicians that receive) such payments are liable for CMPs of up to $2,000 per patient covered by the payments. See

[7]In addition, nonprofit hospital arrangements raise issues of private inurement and private benefit under the Internal Revenue Service's income tax regulations in connection with section 501(c)(3) of the Internal Revenue Code. See Rev. Rul. 69-383, 1969-2 C.B. 113. We express no opinion on the application of the Internal Revenue Code to the Proposed Arrangement.

id. There is no requirement that the prohibited payment be tied to a specific patient or to a reduction in medically necessary care. The CMP applies only to reductions or limitations of items or services provided to Medicare and Medicaid fee-for-service beneficiaries.[8]

The CMP prohibits payments by hospitals to physicians that may induce physicians to reduce or limit items or services furnished to their Medicare and Medicaid patients. A threshold inquiry is whether the Proposed Arrangement will induce physicians to reduce or limit items or services. Given the specificity of the Proposed Arrangement, it is possible to review the proposed opportunities for savings individually and evaluate their potential impact on patient care.

Having reviewed the twelve recommendations, we conclude that the recommendations implicate the CMP. Simply put, the recommendations under the Proposed Arrangement regarding standardization of devices and limitations on the use of vascular closure devices constitute an inducement to reduce or limit the current medical practice at the Hospital. Thus, we find that the CMP would apply to the Proposed Arrangement. We recognize that the current medical practice may involve care that exceeds the requirements of medical necessity. However, whether the current medical practice reflects necessity or prudence is irrelevant for purposes of the CMP.

Notwithstanding, the Proposed Arrangement has several features that, in combination, provide sufficient safeguards so that we would not seek sanctions against the Requestors under sections 1128A(b)(1)-(2) of the Act.

First, the specific cost-saving actions and resulting savings are clearly and separately identified. The transparency of the Proposed Arrangement will allow for public scrutiny and individual physician accountability for any adverse effects of the Proposed Arrangement, including any difference in treatment among patients based on nonclinical indicators. The transparency of the incentives for specific actions and specific procedures will also facilitate accountability through the medical-legal professional liability system.

Second, the Requestors have proffered credible medical support for the position that implementation of the recommendations will not adversely affect patient care. The Proposed Arrangement will be periodically reviewed by the Requestors to confirm that

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[8]Physician incentive arrangements related to Medicare risk-based managed care contracts, similar Medicaid contracts, and Medicare Advantage plans (formerly Medicare + Choice) are subject to regulation by the Secretary pursuant to sections 1876(i)(8), 1903(m)(2)(A)(x), and 1852(j)(4) of the Act (respectively), in lieu of being subject to sections 1128A(b)(1)-(2). See OIG letter regarding hospital-physician incentive plans for Medicare and Medicaid beneficiaries enrolled in managed care plans (dated August 19, 1999), available at http://oig.hhs.gov/fraud/docs/alertsandbulletins/gsletter.htm. See also 42 C.F.R. § 417.479 (Medicare HMOs or competitive medical plans); 42 C.F.R. § 422.208 (Medicare Advantage plans); 42 C.F.R. § 438.6 (Medicaid risk plans).

the Proposed Arrangement is not having an adverse impact on clinical care.[9]

Third, the payments under the Proposed Arrangement are based on all procedures regardless of the patients' insurance coverage, subject to the cap on payment for Federal health care program procedures. Moreover, the procedures to which the Proposed Arrangement applies are not disproportionately performed on Federal health care program beneficiaries. Additionally, the cost savings are calculated on the Hospital's actual out-of-pocket acquisition costs, not an accounting convention.

Fourth, the Proposed Arrangement protects against inappropriate reductions in services by utilizing objective historical and clinical measures to establish baseline thresholds beyond which no savings accrue to the Cardiology Group. The Requestors have certified that these baseline measures are reasonably related to the Hospital's or comparable hospitals' practices and patient populations. These safeguards are action-specific and not simply based on isolated patient outcome data unrelated to the specific changes in catheterization laboratory practices.

Fifth, the product standardization portion of the Proposed Arrangement further protects against inappropriate reductions in services by ensuring that individual physicians will still have available the same selection of devices after implementation of the Proposed Arrangement as before. The Proposed Arrangement is designed to produce savings through inherent clinical and fiscal value and not from restricting the availability of devices.

Sixth, the Hospital and the Cardiology Group will provide written disclosures of their involvement in the Proposed Arrangement to patients whose care may be affected by the Proposed Arrangement and will provide patients an opportunity to review the cost savings recommendations prior to admission to the Hospital (or, where pre-admission consent is impracticable, prior to consenting to the procedure). While we do not believe that, standing alone, such disclosures offer sufficient protection from program or patient abuse, effective and meaningful disclosure offers some protection against possible abuses of patient trust.[10]

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[9]We have had the Proposed Arrangement reviewed by a government medical expert who concluded that the proposed cost savings measures, as described in the advisory opinion request and supplemental submissions, should not adversely affect patient care. For purposes of this opinion, however, we rely solely on the Requestors' certifications and nothing in this advisory opinion should be construed as an endorsement or conclusion as to the medical propriety of the specific activities being undertaken as part of the Proposed Arrangement.

[10]Ordinarily, we would expect patient disclosures to be coupled with patient satisfaction surveys that closely monitor patient perceptions of their care. However, in the context of the Proposed Arrangement, which focuses on items and medications used in procedures, we believe that patient satisfaction surveys would not be effective.

Seventh, the financial incentives under the Proposed Arrangement are reasonably limited in duration and amount.

Eighth, because the Cardiology Group's profits are distributed to its members on a per capita basis, any incentive for an individual cardiologist to generate disproportionate cost savings is mitigated.

Our decision not to impose sanctions on the Requestors in connection with the Proposed Arrangement is an exercise of our discretion and is consistent with our Special Advisory Bulletin on "Gainsharing Arrangements and CMPs for Hospital Payments to Physicians to Reduce or Limit Services to Beneficiaries" (July 1999) (the "Special Advisory Bulletin"). We reiterate that the CMP applies to any payment by a hospital to a physician that is intended to induce the reduction or limitation of items or services to Medicare or Medicaid patients under the physician's direct clinical care. The Proposed Arrangement is markedly different from many "gainsharing" plans, particularly those that purport to pay physicians a percentage of generalized cost savings not tied to specific, identifiable cost-lowering activities. Importantly, the Proposed Arrangement sets out the specific actions to be taken and ties the remuneration to the actual, verifiable cost savings attributable to those actions. This transparency allows an assessment of the likely effect of the Proposed Arrangement on quality of care and ensures that the identified actions will be the cause of the savings.

By contrast, many gainsharing plans contain features that heighten the risk that payments will lead to inappropriate reductions or limitations of services. These features include, but are not limited to, the following:

- There is no demonstrable direct connection between individual actions and any reduction in the hospital's out-of-pocket costs (and any corresponding "gainsharing" payment).

- The individual actions that would give rise to the savings are not identified with specificity.

- There are insufficient safeguards against the risk that other, unidentified actions, such as premature hospital discharges, might actually account for any "savings."

- The quality of care indicators are of questionable validity and statistical significance.

- There is no independent verification of cost savings, quality of care indicators, or other essential aspects of the arrangement.

Simply put, many "gainsharing" plans present substantial risks for both patient and program abuse – risks that are not present in the Proposed Arrangement. Given the limited duration and scope of the Proposed Arrangement, the safeguards provide

sufficient protections against patient and program abuse. Other arrangements, including those that are longer in duration or more expansive in scope than the Proposed Arrangement, are likely to require additional or different safeguards.

B. The Anti-Kickback Statute

The anti-kickback statute makes it a criminal offense knowingly and willfully to offer, pay, solicit, or receive any remuneration to induce or reward referrals of items or services reimbursable by a Federal health care program. See section 1128B(b) of the Act. Where remuneration is paid purposefully to induce or reward referrals of items or services payable by a Federal health care program, the anti-kickback statute is violated. By its terms, the statute ascribes criminal liability to parties on both sides of an impermissible "kickback" transaction. For purposes of the anti-kickback statute, "remuneration" includes the transfer of anything of value, directly or indirectly, overtly or covertly, in cash or in kind.

The statute has been interpreted to cover any arrangement where one purpose of the remuneration was to obtain money for the referral of services or to induce further referrals. United States v. Kats, 871 F.2d 105 (9th Cir. 1989); United States v. Greber, 760 F.2d 68 (3d Cir.), cert. denied, 474 U.S. 988 (1985). Violation of the statute constitutes a felony punishable by a maximum fine of $25,000, imprisonment up to five years, or both. Conviction will also lead to automatic exclusion from Federal health care programs, including Medicare and Medicaid. Where a party commits an act described in section 1128B(b) of the Act, the OIG may initiate administrative proceedings to impose civil monetary penalties on such party under section 1128A(a)(7) of the Act. The OIG may also initiate administrative proceedings to exclude such party from the Federal health care programs under section 1128(b)(7) of the Act.

The Department of Health and Human Services has promulgated safe harbor regulations that define practices that are not subject to the anti-kickback statute because such practices would be unlikely to result in fraud or abuse. See 42 C.F.R. § 1001.952. The safe harbors set forth specific conditions that, if met, assure entities involved of not being prosecuted or sanctioned for the arrangement qualifying for the safe harbor. However, safe harbor protection is afforded only to those arrangements that precisely meet all of the conditions set forth in the safe harbor.

The safe harbor for personal services and management contracts, 42 C.F.R. §1001.952(d), is potentially applicable to the Proposed Arrangement. In relevant part for purposes of this advisory opinion, the personal services safe harbor requires that the aggregate compensation paid for the services be set in advance and consistent with fair market value in arm's-length transactions. The Proposed Arrangement would not fit in the safe harbor because the Cardiology Group will be paid on a percentage basis, and thus the compensation would not be set in advance. However, the absence of safe harbor protection is not fatal. Instead, the Proposed Arrangement must be subject to case-by-case evaluation.

Like any compensation arrangement between a hospital and a physician who admits or refers patients to such hospital, we are concerned that the Proposed Arrangement could be used to disguise remuneration from the Hospital to reward or induce referrals by the Cardiology Group. Specifically, the Proposed Arrangement could encourage the cardiologists to admit Federal health care program patients to the Hospital, since the cardiologist would receive not only their Medicare Part B professional fee, but also, indirectly, a share of the Hospital's payment, depending on cost savings. In other words, the more procedures a cardiologist performs at the Hospital, the more money he or she is likely to receive under the Proposed Arrangement.

While we believe the Proposed Arrangement could result in illegal remuneration if the requisite intent to induce referrals were present, we would not impose sanctions in the particular circumstances presented here and as qualified below.

First, the circumstances and safeguards of the Proposed Arrangement reduce the likelihood that the arrangement will be used to attract referring physicians or to increase referrals from existing physicians. Specifically, participation in the Proposed Arrangement will be limited to cardiologists already on the medical staff, thus limiting the likelihood that the Proposed Arrangement will attract other cardiologists. In addition, the potential savings derived from procedures for Federal health care program beneficiaries will be capped based on the prior year's admissions of Federal health care program beneficiaries. Finally, the contract term will be limited to one year, reducing any incentive to switch facilities, and admissions will be monitored for changes in severity, age, or payor. Thus, while the incentive to refer will not necessarily be eliminated, it will be substantially reduced.

Second, the structure of the Proposed Arrangement eliminates the risk that the Proposed Arrangement will be used to reward cardiologists or other physicians who refer patients to the Cardiology Group or its cardiologists. The Cardiology Group is the sole participant in the Proposed Arrangement and is composed entirely of cardiologist; no surgeons or other physicians are members of the Cardiology Group or share in its profit distributions. Within the Cardiology Group, profits are distributed to its members on a per capita basis, mitigating any incentive for an individual cardiologist to generate disproportionate cost savings.

Third, the Proposed Arrangement sets out with specificity the particular actions that will generate the cost savings on which the payments are based. The recommendations in the Practice Patterns Report represent a change in catheterization laboratory practice, for which the cardiologist is responsible and will have liability exposure. The product standardization and limitation on use of vascular closure devices each carry some increased liability risk for the physicians. It is not unreasonable for the cardiologist to receive compensation for the increased risk from the proposed change in practice. Moreover, the payments will represent a portion of one year's worth of cost savings and will be limited in amount (i.e., the aggregate cap), duration (i.e., the limited contract term), and scope (i.e., the total savings that can be achieved from the implementation of any one recommendation are limited by appropriate utilization levels). The payments

under the Proposed Arrangement do not appear unreasonable, given, among other things, the nature of the actions required of the physicians to implement the twelve recommended actions, the specificity of the payment formula, and the cap on total remuneration to the Cardiology Group.[11] We caution that payments of 50% of cost savings in other arrangements, including multi-year arrangements or arrangements with generalized cost savings formulae, could well lead to a different result.

In light of these circumstances and safeguards, the Proposed Arrangement poses a low risk of fraud or abuse under the anti-kickback statute.

III. CONCLUSION

Notwithstanding the foregoing, we reiterate our concerns regarding many arrangements between hospitals and physicians to share cost savings. Improperly designed or implemented arrangements risk adversely affecting patient care and could be vehicles to disguise payments for referrals. For example, an arrangement that cannot be adequately and accurately measured for quality of care would pose a high risk of fraud or abuse, as would one that rewards physicians based on overall cost savings without accountability for specific cost reduction measures. Moreover, arrangements structured so as to pose a heightened potential for patient steering and unfair competition would be considered suspect. In short, this opinion is predicated on the specific arrangement posed by the Requestors and is limited to that specific arrangement. Other apparently similar arrangements could raise different concerns and lead to a different result.

Based on the facts certified in your request for an advisory opinion and supplemental submissions, we conclude: (i) the Proposed Arrangement would constitute an improper payment to induce reduction or limitation of services pursuant to sections 1128A(b)(1)-(2) of the Act, but that the OIG would not impose sanctions under sections 1128A(b)(1)-(2) on the Requestors in connection with the Proposed Arrangement; and (ii) the Proposed Arrangement would potentially generate prohibited remuneration under the anti-kickback statute, if the requisite intent to induce or reward referrals of Federal health care program business were present, but that the OIG would not impose administrative sanctions on the Requestors under sections 1128(b)(7) or 1128A(a)(7) of the Act (as those sections relate to the commission of acts described in section 1128B(b) of the Act) in connection with the Proposed Arrangement.

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[11]We are precluded by statute from opining on whether fair market value shall be or was paid for goods, services, or property. See 42 U.S.C. § 1320a-7d(b)(3)(A). While the Requestors have certified that the payments under the Proposed Arrangement are consistent with fair market value, we do not rely on that certification in this opinion, nor have we have made an independent fair market value assessment.

IV. LIMITATIONS

The limitations applicable to this opinion include the following:

- This advisory opinion is issued only to [names redacted], the requestors of this opinion. This advisory opinion has no application to, and cannot be relied upon by, any other individual or entity.

- This advisory opinion may not be introduced into evidence in any matter involving an entity or individual that is not a requestor to this opinion.

- This advisory opinion is applicable only to the statutory provisions specifically noted above. No opinion is expressed or implied herein with respect to the application of any other Federal, state, or local statute, rule, regulation, ordinance, or other law that may be applicable to the Proposed Arrangement, including, without limitation, the physician self-referral law, section 1877 of the Act.

- This advisory opinion will not bind or obligate any agency other than the U.S. Department of Health and Human Services.

- This advisory opinion is limited in scope to the specific arrangement described in this letter and has no applicability to other arrangements, even those that appear similar in nature or scope.

- No opinion is expressed herein regarding the liability of any party under the False Claims Act or other legal authorities for any improper billing, claims submission, cost reporting, or related conduct.

This opinion is also subject to any additional limitations set forth at 42 C.F.R. Part 1008.

The OIG will not proceed against the Requestors with respect to any action that is part of the Proposed Arrangement taken in good faith reliance upon this advisory opinion, as long as all of the material facts have been fully, completely, and accurately presented, and the Proposed Arrangement in practice comports with the information provided. The OIG reserves the right to reconsider the questions and issues raised in this advisory opinion and, where the public interest requires, to rescind, modify, or terminate this opinion. In the event that this advisory opinion is modified or terminated, the OIG will not proceed against the Requestors with respect to any action taken in good faith reliance upon this advisory opinion, where all of the relevant facts were fully, completely, and accurately presented, and where such action was promptly

discontinued upon notification of the modification or termination of this advisory opinion. An advisory opinion may be rescinded only if the relevant and material facts have not been fully, completely, and accurately disclosed to the OIG.

Sincerely,

/s/

Lewis Morris
Chief Counsel to the Inspector General

[Appendix A Redacted]

[*We redact certain identifying information and certain potentially privileged, confidential, or proprietary information associated with the individual or entity, unless otherwise approved by the requestors.*]

Issued: February 18, 2005

Posted: February 25, 2005

[names and addresses redacted]

Re: **OIG Advisory Opinion No. 05-06**

Ladies and Gentlemen:

We are writing in response to your request for an advisory opinion concerning a proposed arrangement in which a hospital will share with a group of cardiac surgeons a percentage of the hospital's cost savings arising from the surgeons' implementation of a number of cost reduction measures in certain surgical procedures (the "Proposed Arrangement"). The cost savings will be measured based on the surgeons' use of specific supplies during designated cardiac surgery procedures. You have inquired whether the Proposed Arrangement would constitute grounds for sanctions arising under: (i) the civil monetary penalty for a hospital's payment to a physician to induce reductions or limitations of services to Medicare or Medicaid beneficiaries under the physician's direct care, sections 1128A(b)(1)-(2) of the Social Security Act (the "Act"); or (ii) the exclusion authority at section 1128(b)(7) of the Act or the civil monetary penalty provision at section 1128A(a)(7) of the Act, as those sections relate to the commission of acts described in section 1128B(b) of the Act, the anti-kickback statute.

You have certified that all of the information provided in your request, including all supplementary letters, is true and correct and constitutes a complete description of the relevant facts and agreements among the parties.

In issuing this opinion, we have relied solely on the facts and information presented to us. We have not undertaken an independent investigation of such information. This opinion is limited to the facts presented. If material facts have not been disclosed or have been misrepresented, this opinion is without force and effect.

Based on the information provided and the totality of the facts as described and certified in your request for an advisory opinion and supplemental submissions, we conclude that: (i) the Proposed Arrangement would constitute an improper payment to induce reduction

or limitation of services pursuant to sections 1128A(b)(1)-(2) of the Act, but that the Office of Inspector General ("OIG") would not impose sanctions on the requestors of this advisory opinion, [names redacted] (the "Requestors"), in connection with the Proposed Arrangement; and (ii) the Proposed Arrangement would potentially generate prohibited remuneration under the anti-kickback statute, if the requisite intent to induce or reward referrals of Federal health care program business were present, but that the OIG would not impose administrative sanctions on the Requestors under sections 1128(b)(7) or 1128A(a)(7) of the Act (as those sections relate to the commission of acts described in section 1128B(b) of the Act) in connection with the Proposed Arrangement.

This opinion may not be relied on by any persons other than the Requestors and is further qualified as set out in Part IV below and in 42 C.F.R. Part 1008.

I. FACTUAL BACKGROUND

A. Parties

The Hospital. [Name redacted] (the "Hospital") is an acute care hospital in [city and state redacted] that offers a broad range of inpatient and outpatient hospital services, including cardiac surgery services. The Hospital is a participating provider in the Medicare and Medicaid programs.

The Surgical Group. [Name redacted] (the "Surgical Group") is a professional association composed exclusively of cardiac surgeons who are licensed in [state redacted] and have active medical staff privileges at the Hospital.[1] The cardiac surgeons refer patients to the Hospital for inpatient and outpatient hospital services.

The Program Administrator. The Hospital has engaged [name redacted] (the "Program Administrator") to administer the Proposed Arrangement. The Program Administrator will collect data and analyze and manage the Proposed Arrangement.[2] The Hospital will pay the Program Administrator a monthly fixed fee certified by the Requestors to be fair market value in an arm's-length transaction for services to be provided by the Program Administrator under the Proposed Arrangement. The fee will not be tied in any way to cost savings or the Surgical Group's compensation under the Proposed Arrangement.

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[1] The Surgical Group performs the majority of cardiac surgery cases at the Hospital. The surgeons in the Surgical Group also practice at one other hospital in the region.

[2] The Program Administrator has developed software products that measure cost, quality, and utilization on a national basis. The products are certified by both the American College of Cardiology and the Society of Thoracic Surgery.

B. The Proposed Arrangement

Under the Proposed Arrangement, the Hospital will pay the Surgical Group a share of the first year cost savings directly attributable to specific changes in the Surgical Group's operating room practices, including standardization of certain cardiac devices. The Program Administrator conducted a study of the historic practices at the Hospital's cardiac surgery department and identified twenty-seven specific cost-savings opportunities. The results of the Program Administrator's study of the Surgical Group and the specific cost-savings opportunities are summarized in a "Practice Patterns Report."[3] The Hospital and the Surgical Group have reviewed the Practice Patterns Report for medical appropriateness and each has adopted its recommendations and conclusions.

In general, the Practice Patterns Report recommends that the Surgical Group change current operating room practices to curb inappropriate use or waste of medical supplies. The twenty-seven recommendations can be roughly grouped into four categories.

The first category consists of two recommendations that involve opening packaged items only as needed during a procedure. Most of these "open as needed" items are surgical tray or comparable supplies.

The second category, involving three recommendations, is similar and involves limiting the use of certain surgical supplies, such as gelfoam, surgicel, and vancomycin paste, to an as needed basis (hereafter, the "use as needed" recommendations). The Requestors have certified that the individual surgeon will make a patient-by-patient determination as to whether these items are clinically indicated and that the surgical supplies will still be readily available to the surgeons. The Requestors have further certified that any resulting limitations on the use of these products will not adversely affect patient care.

The third category, involving eleven recommendations, consists of the substitution, in whole or in part, of less costly items for items currently being used by the surgeons (hereafter, the "product substitution" recommendations). In this case, the substitutions involve types of items and services for which a product substitution will have no appreciable clinical significance (e.g., substituting disposable head supports, disposable k-thermia blankets, and instrument pouches). For example, currently a foam donut is used in each surgical case to support the patient's head. Under the Proposed Arrangement, surgeons would be asked to utilize a less expensive reusable head support that has similar characteristics to the surgeons' historic preference.

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[3] The Practice Patterns Report for the Surgical Group, dated October 2004, is attached to this advisory opinion as Appendix A. The Requestors' original submission included additional cost savings recommendations that posed an unacceptable risk of fraud and abuse. The Requestors withdrew those recommendations from the Proposed Arrangement.

The final category, involving eleven recommendations, consists of product standardization of certain cardiac devices and supplies where medically appropriate. For this category, the Surgical Group would be required to work in conjunction with the Hospital to evaluate and clinically review vendors and products.[4] The Surgical Group would agree to use the selected products where medically appropriate, which may require additional training or changes in clinical practice.

The Proposed Arrangement contains several safeguards intended to protect against inappropriate reductions in services. With respect to the substitution recommendations, the Proposed Arrangement would utilize objective historical and clinical measures reasonably related to the practices and the patient population at the Hospital to establish a "floor" beyond which no savings would accrue to the Surgical Group. For example, surgicel is currently utilized on 28% of the cases specified under the Proposed Arrangement. According to the Program Administrator, national data indicates a best practice usage of 5% for surgicel. Thus, the Program Administrator has set a 5% floor for this recommendation. The Surgical Group will receive no share of any savings resulting from the reduction in use of surgicel beyond the 5% floor. With respect to the product substitution recommendations in the Proposed Arrangement, as the identified substitutions[5] will have no appreciable clinical significance, no floors are set.[6]

Importantly, with respect to the product standardization recommendations, the Requestors have certified that the individual surgeons will make a patient-by-patient determination of the most appropriate devices and supplies and the availability of the full range of these items will not be compromised by the product standardization. The Requestors have further certified that individual physicians will still have available the same selection of devices and supplies after implementation of the Proposed Arrangement as before and that the economies gained through the Proposed Arrangement will result from inherent clinical and fiscal value and not from restricting the availability of devices and supplies.

According to the Program Administrator, if implemented in accordance with the Practice Patterns Report's specifications, the twenty-seven recommendations would present substantial cost savings opportunities for the Hospital without adversely impacting the quality of patient care.

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[4]We note that the Practice Patterns Report identifies with specificity the vendors and products at issue.

[5]The Practice Patterns Report clearly identifies with specificity each substitution recommendation under this category.

[6]We note that for product substitution recommendations that are of clinical significance, we would require additional safeguards, such as the establishment of quality thresholds beyond which no cost savings would be credited.

The Hospital will pay the Surgical Group 50% of the cost savings achieved by implementing the twenty-seven recommendations in the Practice Patterns Report for a period of one year. At the end of the year, cost savings will be calculated separately for each of the twenty-seven recommendations; this will preclude shifting of cost savings and ensure that savings generated by utilization beyond the set targets, as applicable, will not be credited to the Surgical Group. This payment will constitute the entire compensation paid to the Surgical Group for services performed under the contract memorializing the Proposed Arrangement between the Surgical Group and the Hospital. For purposes of calculating the payment to the Surgical Group, the cost savings will be calculated by subtracting the actual costs incurred for the items specified in the twenty-seven recommendations when used by surgeons in the Surgical Group during the specified surgical procedures (the "current year costs"[7]) from the historic costs for the same items when used during comparable surgical procedures in the base year (the "base year costs"[8]). The current year costs will be adjusted to account for any inappropriate reductions in use of items beyond the targets set in the Practice Patterns Report. The payment to the Surgical Group will be 50% of the difference between the adjusted current year costs and base year costs, if any.

The Hospital will make an aggregate payment to the Surgical Group, which distributes its profits to each of its members on a per capita basis. Payments to the Surgical Group will also be subject to the following limitations:

- If the volume of procedures payable by a Federal health care program in the current year exceeds the volume of like procedures payable by a Federal health care program performed in the base year, there will be no sharing of cost savings for the additional procedures.

- To minimize the surgeons' financial incentive to steer more costly patients to other hospitals, the case severity, ages, and payors of the patient population treated under the Proposed Arrangement will be monitored by a committee composed of representatives of the Requestors, using generally-accepted standards. If there are significant changes from historical measures, the surgeon at issue will be terminated from participation in the Proposed Arrangement.

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[7]The current year will be the twelve-month term of the contract for which the Surgical Group will be compensated under the Proposed Arrangement.

[8]The "base year" will be the twelve months preceding the effective date of the contract. For purposes of this opinion, the Proposed Arrangement is limited to the one-year term of the contract; accordingly, this opinion is without force and effect with respect to any future renewal or extension of the Proposed Arrangement. Notwithstanding, we note that any renewal or extension of the Proposed Arrangement should incorporate updated base year costs.

- The aggregate payment to the Surgical Group will not exceed 50% of the projected cost savings identified in the Practice Patterns Report.

The Hospital and the Surgical Group will document the activities and the payment methodology under the Proposed Arrangement and will make the documentation available to the Secretary of the United States Department of Health and Human Services, upon request. In addition, the Hospital and the Surgical Group will disclose the Proposed Arrangement to the patient, including the fact that the Surgical Group's compensation is based on a percentage of the Hospital's cost savings. The disclosure will be made to the patient before the patient is admitted to the Hospital for a procedure covered by the Proposed Arrangement; if pre-admission disclosure is impracticable (e.g., the patient is admitted for an unscheduled procedure or the need for the procedure is determined after admission), the disclosure will be made before the patient consents to the surgery. The disclosures will be in writing, and patients will have an opportunity, if desired, to review details of the Proposed Arrangement, including the specific cost savings measures applicable to the patient's surgery.

II. LEGAL ANALYSIS

Arrangements like the Proposed Arrangement are designed to align incentives by offering physicians a portion of a hospital's cost savings in exchange for implementing cost saving strategies. Under the current reimbursement system, the burden of these costs falls on hospitals, not physicians. Payments to physicians based on cost savings may be intended to motivate them to reduce hospital costs associated with procedures performed by physicians at the hospitals.

Properly structured, arrangements that share cost savings can serve legitimate business and medical purposes. Specifically, properly structured arrangements may increase efficiency and reduce waste, thereby potentially increasing a hospital's profitability. However, such arrangements can potentially influence physician judgment to the detriment of patient care. Our concerns include, but are not limited to, the following: (i) stinting on patient care; (ii) "cherry picking" healthy patients and steering sicker (and more costly) patients to hospitals that do not offer such arrangements; (iii) payments in exchange for patient referrals; and (iv) unfair competition (a "race to the bottom") among hospitals offering cost savings programs to foster physician loyalty and to attract more referrals.

Hospital cost savings programs in general, and the Proposed Arrangement in particular, may implicate at least three Federal legal authorities: (i) the civil monetary penalty for reductions or limitations of direct patient care services provided to Federal health care program beneficiaries, sections 1128A(b)(1)-(2) of the Act; (ii) the anti-kickback statute, section 1128B(b) of the Act; and (iii) the physician self-referral law, section 1877 of the

Act.[9] We address the first two of these authorities; section 1877 of the Act falls outside the scope of the OIG's advisory opinion authority. We express no opinion on the application of section 1877 of the Act to the Proposed Arrangement.

A. The Civil Monetary Penalty, Sections 1128A(b)(1)-(2) of the Act

Sections 1128A(b)(1)-(2) of the Act establish a civil monetary penalty ("CMP") against any hospital or critical access hospital that knowingly makes a payment directly or indirectly to a physician (and any physician that receives such a payment) as an inducement to reduce or limit items or services to Medicare or Medicaid beneficiaries under the physician's direct care. Hospitals that make (and physicians that receive) such payments are liable for CMPs of up to $2,000 per patient covered by the payments. See id. There is no requirement that the prohibited payment be tied to a specific patient or to a reduction in medically necessary care. The CMP applies only to reductions or limitations of items or services provided to Medicare and Medicaid fee-for-service beneficiaries.[10]

The CMP prohibits payments by hospitals to physicians that may induce physicians to reduce or limit items or services furnished to their Medicare and Medicaid patients. A threshold inquiry is whether the Proposed Arrangement will induce physicians to reduce or limit items or services. Given the specificity of the Proposed Arrangement, it is possible to review the proposed opportunities for savings individually and evaluate their potential impact on patient care.

Having reviewed the twenty-seven individual recommendations, we conclude that, except for the unopened surgical tray items and the product substitutions (discussed in more detail below), the recommendations implicate the CMP. Simply put, with respect to the recommendations regarding the "use as needed" surgical supplies and the product standardization, the Proposed Arrangement constitutes an inducement to reduce or limit

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[9]In addition, nonprofit hospital arrangements raise issues of private inurement and private benefit under the Internal Revenue Service's income tax regulations in connection with section 501(c)(3) of the Internal Revenue Code. See Rev. Rul. 69-383, 1969-2 C.B. 113. We express no opinion on the application of the Internal Revenue Code to the Proposed Arrangement.

[10]Physician incentive arrangements related to Medicare risk-based managed care contracts, similar Medicaid contracts, and Medicare Advantage plans (formerly Medicare + Choice) are subject to regulation by the Secretary pursuant to sections 1876(i)(8), 1903(m)(2)(A)(x), and 1852(j)(4) of the Act (respectively), in lieu of being subject to sections 1128A(b)(1)-(2). See OIG letter regarding hospital-physician incentive plans for Medicare and Medicaid beneficiaries enrolled in managed care plans (dated August 19, 1999), available at http://oig.hhs.gov/fraud/docs/alertsandbulletins/gsletter.htm. See also 42 C.F.R. § 417.479 (Medicare HMOs or competitive medical plans); 42 C.F.R. § 422.208 (Medicare Advantage plans); 42 C.F.R. § 438.6 (Medicaid risk plans).

the current medical practice at the Hospital. We recognize that the current medical practice may involve care that exceeds the requirements of medical necessity. However, whether the current medical practice reflects necessity or prudence is irrelevant for purposes of the CMP.

With respect to the recommendations regarding "open as needed" surgical tray items and product substitutions, we reach a different conclusion. To the extent that the sole delay in providing items or services is the insubstantial time it takes to open a package of supplies readily available in the operating room, we believe there will be no perceptible reduction or limitation in the provision of items or services to patients sufficient to trigger the CMP. With respect to the specific product substitution recommendations, the identified substitutions will have no appreciable clinical significance; therefore, we believe there will be no perceptible reduction or limitation in the provision of items or services to patients sufficient to trigger the CMP.

In sum, while the recommendations for the "open as needed" surgical tray items and the specific product substitutions do not run afoul of the CMP, we find that the CMP would apply to the remaining recommendations involving limitations on use of certain surgical supplies and product standardization. Notwithstanding, the Proposed Arrangement has several features that, in combination, provide sufficient safeguards so that we would not seek sanctions against the Requestors under sections 1128A(b)(1)-(2) of the Act.

First, the specific cost-saving actions and resulting savings are clearly and separately identified. The transparency of the Proposed Arrangement will allow for public scrutiny and individual physician accountability for any adverse effects of the Proposed Arrangement, including any difference in treatment among patients based on nonclinical indicators. The transparency of the incentives for specific actions and specific procedures will also facilitate accountability through the medical-legal professional liability system.

Second, the Requestors have proffered credible medical support for the position that implementation of the recommendations will not adversely affect patient care. The Proposed Arrangement will be periodically reviewed by the Requestors to confirm that the Proposed Arrangement is not having an adverse impact on clinical care.[11]

Third, the payments under the Proposed Arrangement are based on all surgeries regardless of the patients' insurance coverage, subject to the cap on payment for Federal health care program procedures. Moreover, the surgical procedures to which the

[11]We have had the Proposed Arrangement reviewed by a government medical expert who concluded that the proposed cost savings measures, as described in the advisory opinion request and supplemental submissions, should not adversely affect patient care. For purposes of this opinion, however, we rely solely on the Requestors' certifications and nothing in this advisory opinion should be construed as an endorsement or conclusion as to the medical propriety of the specific activities being undertaken as part of the Proposed Arrangement.

Proposed Arrangement applies are not disproportionately performed on Federal health care program beneficiaries. Additionally, the cost savings are calculated on the Hospital's actual out-of-pocket acquisition costs, not an accounting convention.

Fourth, the Proposed Arrangement protects against inappropriate reductions in services by utilizing objective historical and clinical measures to establish baseline thresholds beyond which no savings accrue to the Surgical Group. The Requestors have certified that these baseline measures are reasonably related to the Hospital's or comparable hospitals' practices and patient populations. These safeguards are action-specific and not simply based on isolated patient outcome data unrelated to the specific changes in operating room practices.

Fifth, the product standardization portion of the Proposed Arrangement further protects against inappropriate reductions in services by ensuring that individual physicians will still have available the same selection of cardiac devices after implementation of the Proposed Arrangement as before. The Proposed Arrangement is designed to produce savings through inherent clinical and fiscal value and not from restricting the availability of devices.

Sixth, the Hospital and the Surgical Group will provide written disclosures of their involvement in the Proposed Arrangement to patients whose care may be affected by the Proposed Arrangement and will provide patients an opportunity to review the cost savings recommendations prior to admission to the Hospital (or, where pre-admission consent is impracticable, prior to consenting to surgery). While we do not believe that, standing alone, such disclosures offer sufficient protection from program or patient abuse, effective and meaningful disclosure offers some protection against possible abuses of patient trust.[12]

Seventh, the financial incentives under the Proposed Arrangement are reasonably limited in duration and amount.

Eighth, because the Surgical Group's profits are distributed to its members on a per capita basis, any incentive for an individual surgeon to generate disproportionate cost savings is mitigated.

Our decision not to impose sanctions on the Requestors in connection with the Proposed Arrangement is an exercise of our discretion and is consistent with our Special Advisory Bulletin on "Gainsharing Arrangements and CMPs for Hospital Payments to Physicians to Reduce or Limit Services to Beneficiaries" (July 1999) (the "Special Advisory Bulletin"). We reiterate that the CMP applies to any payment by a hospital to a physician

[12]Ordinarily, we would expect patient disclosures to be coupled with patient satisfaction surveys that closely monitor patient perceptions of their care. However, in the context of the Proposed Arrangement, which focuses on items and medications used in operating rooms, we believe that patient satisfaction surveys would not be effective.

that is intended to induce the reduction or limitation of items or services to Medicare or Medicaid patients under the physician's direct clinical care. The Proposed Arrangement is markedly different from many "gainsharing" plans, particularly those that purport to pay physicians a percentage of generalized cost savings not tied to specific, identifiable cost-lowering activities. Importantly, the Proposed Arrangement sets out the specific actions to be taken and ties the remuneration to the actual, verifiable cost savings attributable to those actions. This transparency allows an assessment of the likely effect of the Proposed Arrangement on quality of care and ensures that the identified actions will be the cause of the savings.

By contrast, many gainsharing plans contain features that heighten the risk that payments will lead to inappropriate reductions or limitations of services. These features include, but are not limited to, the following:

- There is no demonstrable direct connection between individual actions and any reduction in the hospital's out-of-pocket costs (and any corresponding "gainsharing" payment).

- The individual actions that would give rise to the savings are not identified with specificity.

- There are insufficient safeguards against the risk that other, unidentified actions, such as premature hospital discharges, might actually account for any "savings."

- The quality of care indicators are of questionable validity and statistical significance.

- There is no independent verification of cost savings, quality of care indicators, or other essential aspects of the arrangement.

Simply put, many "gainsharing" plans present substantial risks for both patient and program abuse – risks that are not present in the Proposed Arrangement. Given the limited duration and scope of the Proposed Arrangement, the safeguards provide sufficient protections against patient and program abuse. Other arrangements, including those that are longer in duration or more expansive in scope than the Proposed Arrangement, are likely to require additional or different safeguards.

B. The Anti-Kickback Statute

The anti-kickback statute makes it a criminal offense knowingly and willfully to offer, pay, solicit, or receive any remuneration to induce or reward referrals of items or services reimbursable by a Federal health care program. See section 1128B(b) of the Act. Where remuneration is paid purposefully to induce or reward referrals of items or services payable by a Federal health care program, the anti-kickback statute is violated. By its terms, the statute ascribes criminal liability to parties on both sides of an impermissible

"kickback" transaction. For purposes of the anti-kickback statute, "remuneration" includes the transfer of anything of value, directly or indirectly, overtly or covertly, in cash or in kind.

The statute has been interpreted to cover any arrangement where one purpose of the remuneration was to obtain money for the referral of services or to induce further referrals. United States v. Kats, 871 F.2d 105 (9th Cir. 1989); United States v. Greber, 760 F.2d 68 (3d Cir.), cert. denied, 474 U.S. 988 (1985). Violation of the statute constitutes a felony punishable by a maximum fine of $25,000, imprisonment up to five years, or both. Conviction will also lead to automatic exclusion from Federal health care programs, including Medicare and Medicaid. Where a party commits an act described in section 1128B(b) of the Act, the OIG may initiate administrative proceedings to impose civil monetary penalties on such party under section 1128A(a)(7) of the Act. The OIG may also initiate administrative proceedings to exclude such party from the Federal health care programs under section 1128(b)(7) of the Act.

The Department of Health and Human Services has promulgated safe harbor regulations that define practices that are not subject to the anti-kickback statute because such practices would be unlikely to result in fraud or abuse. See 42 C.F.R. § 1001.952. The safe harbors set forth specific conditions that, if met, assure entities involved of not being prosecuted or sanctioned for the arrangement qualifying for the safe harbor. However, safe harbor protection is afforded only to those arrangements that precisely meet all of the conditions set forth in the safe harbor.

The safe harbor for personal services and management contracts, 42 C.F.R. §1001.952(d), is potentially applicable to the Proposed Arrangement. In relevant part for purposes of this advisory opinion, the personal services safe harbor requires that the aggregate compensation paid for the services be set in advance and consistent with fair market value in arm's-length transactions. The Proposed Arrangement would not fit in the safe harbor because the Surgical Group will be paid on a percentage basis, and thus the compensation would not be set in advance. However, the absence of safe harbor protection is not fatal. Instead, the Proposed Arrangement must be subject to case-by-case evaluation.

Like any compensation arrangement between a hospital and a physician who admits or refers patients to such hospital, we are concerned that the Proposed Arrangement could be used to disguise remuneration from the Hospital to reward or induce referrals by the Surgical Group. Specifically, the Proposed Arrangement could encourage the surgeons to admit Federal health care program patients to the Hospital, since the surgeons would receive not only their Medicare Part B professional fee, but also, indirectly, a share of the Hospital's payment, depending on cost savings. In other words, the more procedures a surgeon performs at the Hospital, the more money he or she is likely to receive under the Proposed Arrangement.

While we believe the Proposed Arrangement could result in illegal remuneration if the requisite intent to induce referrals were present, we would not impose sanctions in the particular circumstances presented here and as qualified below.

First, the circumstances and safeguards of the Proposed Arrangement reduce the likelihood that the arrangement will be used to attract referring physicians or to increase referrals from existing physicians. Specifically, participation in the Proposed Arrangement will be limited to surgeons already on the medical staff, thus limiting the likelihood that the Proposed Arrangement will attract other surgeons. In addition, the potential savings derived from procedures for Federal health care program beneficiaries will be capped based on the prior year's admissions of Federal health care program beneficiaries. Finally, the contract term will be limited to one year, reducing any incentive to switch facilities, and admissions will be monitored for changes in severity, age, or payor. Thus, while the incentive to refer will not necessarily be eliminated, it will be substantially reduced.

Second, the structure of the Proposed Arrangement eliminates the risk that the Proposed Arrangement will be used to reward cardiologists or other physicians who refer patients to the Surgical Group or its surgeons. The Surgical Group is the sole participant in the Proposed Arrangement and is composed entirely of cardiac surgeons; no cardiologists or other physicians are members of the Surgical Group or share in its profit distributions. Within the Surgical Group, profits are distributed to its members on a per capita basis, mitigating any incentive for an individual surgeon to generate disproportionate cost savings.

Third, the Proposed Arrangement sets out with specificity the particular actions that will generate the cost savings on which the payments are based. While many of the recommendations in the Practice Patterns Report are simple common sense, they do represent a change in operating room practice, for which the surgeon is responsible and will have liability exposure. While most of the recommendations would appear to present minimal risk, limitation on use of certain surgical supplies and product standardization each carry some increased liability risk for the physicians. It is not unreasonable for the surgeon to receive compensation for the increased risk from the proposed change in practice. Moreover, the payments will represent a portion of one year's worth of cost savings and will be limited in amount (i.e., the aggregate cap), duration (i.e., the limited contract term), and scope (i.e., the total savings that can be achieved from the implementation of any one recommendation are limited by appropriate utilization levels). The payments under the Proposed Arrangement do not appear unreasonable, given, among other things, the nature of the actions required of the physicians to implement the twenty-seven recommended actions, the specificity of the payment formula, and the cap on total remuneration to the Surgical Group.[13] We caution that payments of 50% of cost savings in other arrangements, including multi-year arrangements or arrangements with generalized cost savings formulae, could well lead to a different result.

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[13]We are precluded by statute from opining on whether fair market value shall be or was paid for goods, services, or property. See 42 U.S.C. § 1320a-7d(b)(3)(A). While the Requestors have certified that the payments under the Proposed Arrangement are consistent with fair market value, we do not rely on that certification in this opinion, nor have we have made an independent fair market value assessment.

In light of these circumstances and safeguards, the Proposed Arrangement poses a low risk of fraud or abuse under the anti-kickback statute.

III. CONCLUSION

Notwithstanding the foregoing, we reiterate our concerns regarding many arrangements between hospitals and physicians to share cost savings. Improperly designed or implemented arrangements risk adversely affecting patient care and could be vehicles to disguise payments for referrals. For example, an arrangement that cannot be adequately and accurately measured for quality of care would pose a high risk of fraud or abuse, as would one that rewards physicians based on overall cost savings without accountability for specific cost reduction measures. Moreover, arrangements structured so as to pose a heightened potential for patient steering and unfair competition would be considered suspect. In short, this opinion is predicated on the specific arrangement posed by the Requestors and is limited to that specific arrangement. Other apparently similar arrangements could raise different concerns and lead to a different result.

Based on the facts certified in your request for an advisory opinion and supplemental submissions, we conclude: (i) the Proposed Arrangement would constitute an improper payment to induce reduction or limitation of services pursuant to sections 1128A(b)(1)-(2) of the Act, but that the OIG would not impose sanctions under sections 1128A(b)(1)-(2) on the Requestors in connection with the Proposed Arrangement; and (ii) the Proposed Arrangement would potentially generate prohibited remuneration under the anti-kickback statute, if the requisite intent to induce or reward referrals of Federal health care program business were present, but that the OIG would not impose administrative sanctions on the Requestors under sections 1128(b)(7) or 1128A(a)(7) of the Act (as those sections relate to the commission of acts described in section 1128B(b) of the Act) in connection with the Proposed Arrangement.

IV. LIMITATIONS

The limitations applicable to this opinion include the following:

- This advisory opinion is issued only to [names redacted], the requestors of this opinion. This advisory opinion has no application to, and cannot be relied upon by, any other individual or entity.

- This advisory opinion may not be introduced into evidence in any matter involving an entity or individual that is not a requestor to this opinion.

- This advisory opinion is applicable only to the statutory provisions specifically noted above. No opinion is expressed or implied herein with respect to the application of any other Federal, state, or local statute, rule, regulation, ordinance, or other law that may be applicable to the Proposed

Arrangement, including, without limitation, the physician self-referral law, section 1877 of the Act.

- This advisory opinion will not bind or obligate any agency other than the U.S. Department of Health and Human Services.

- This advisory opinion is limited in scope to the specific arrangement described in this letter and has no applicability to other arrangements, even those that appear similar in nature or scope.

- No opinion is expressed herein regarding the liability of any party under the False Claims Act or other legal authorities for any improper billing, claims submission, cost reporting, or related conduct.

This opinion is also subject to any additional limitations set forth at 42 C.F.R. Part 1008.

The OIG will not proceed against the Requestors with respect to any action that is part of the Proposed Arrangement taken in good faith reliance upon this advisory opinion, as long as all of the material facts have been fully, completely, and accurately presented, and the Proposed Arrangement in practice comports with the information provided. The OIG reserves the right to reconsider the questions and issues raised in this advisory opinion and, where the public interest requires, to rescind, modify, or terminate this opinion. In the event that this advisory opinion is modified or terminated, the OIG will not proceed against the Requestors with respect to any action taken in good faith reliance upon this advisory opinion, where all of the relevant facts were fully, completely, and accurately presented, and where such action was promptly discontinued upon notification of the modification or termination of this advisory opinion. An advisory opinion may be rescinded only if the relevant and material facts have not been fully, completely, and accurately disclosed to the OIG.

Sincerely,

/s/

Lewis Morris
Chief Counsel to the Inspector General

[Appendix A Redacted]

[*We redact certain identifying information and certain potentially privileged, confidential, or proprietary information associated with the individual or entity, unless otherwise approved by the requestors.*]

Issued: November 9, 2006

Posted: November 16, 2006

[names and addresses redacted]

Re: OIG Advisory Opinion No. 06-22

Ladies & Gentlemen:

We are writing in response to your request for an advisory opinion concerning a proposed arrangement in which a hospital will share with a group of cardiac surgeons a percentage of the hospital's cost savings arising from the surgeons' implementation of a number of cost reduction measures in certain surgical procedures (the "Proposed Arrangement"). The cost savings will be measured based on the surgeons' elimination of waste and use of specific supplies during designated cardiac surgery procedures. You have inquired whether the Proposed Arrangement would constitute grounds for sanctions arising under: (i) the civil monetary penalty for a hospital's payment to a physician to induce reductions or limitations of services to Medicare or Medicaid beneficiaries under the physician's direct care, sections 1128A(b)(1)-(2) of the Social Security Act (the "Act"); or (ii) the exclusion authority at section 1128(b)(7) of the Act or the civil monetary penalty provision at section 1128A(a)(7) of the Act, as those sections relate to the commission of acts described in section 1128B(b) of the Act, the anti-kickback statute.

You have certified that all of the information provided in your request, including all supplementary letters, is true and correct and constitutes a complete description of the relevant facts and agreements among the parties.

In issuing this opinion, we have relied solely on the facts and information presented to us. We have not undertaken an independent investigation of such information. This opinion is limited to the facts presented. If material facts have not been disclosed or have been misrepresented, this opinion is without force and effect.

Based on the information provided and the totality of the facts as described and certified in your request for an advisory opinion and supplemental submissions, we conclude that: (i) the Proposed Arrangement would constitute an improper payment to induce reduction or

limitation of services pursuant to sections 1128A(b)(1)-(2) of the Act, but that the Office of Inspector General ("OIG") would not impose sanctions on the requestors of this advisory opinion, [names redacted] (the "Requestors"), in connection with the Proposed Arrangement; and (ii) the Proposed Arrangement would potentially generate prohibited remuneration under the anti-kickback statute, if the requisite intent to induce or reward referrals of Federal health care program business were present, but that the OIG would not impose administrative sanctions on the Requestors under sections 1128(b)(7) or 1128A(a)(7) of the Act (as those sections relate to the commission of acts described in section 1128B(b) of the Act) in connection with the Proposed Arrangement.

This opinion may not be relied on by any persons other than the Requestors and is further qualified as set out in Part IV below and in 42 C.F.R. Part 1008.

I. FACTUAL BACKGROUND

A. Parties

The Hospital. [Name redacted] (the "Hospital") is an acute care hospital in [city and state redacted], that offers a broad range of inpatient and outpatient hospital services, including cardiac surgery services. The Hospital is a participating provider in the Medicare and Medicaid programs.

The Surgeon Group. [Name redacted] (the "Surgeon Group") is a professional association composed exclusively of cardiac surgeons who are licensed in the State of [name redacted] and have active medical staff privileges at the Hospital. The cardiac surgeons refer patients to the Hospital for inpatient and outpatient hospital services. The Surgeon Group is the only group of cardiac surgeons that practices at the Hospital.[1]

The Program Administrator. The Hospital has engaged [name redacted] (the "Program Administrator") to administer the Proposed Arrangement. The Program Administrator will collect data and analyze and manage the Proposed Arrangement.[2] The Hospital will pay the Program Administrator a monthly fixed fee certified by the Requestors to be fair market value in an arm's-length transaction for services to be provided by the Program Administrator under the Proposed Arrangement. The fee will not be tied in any way to cost savings or the Surgeon Group's compensation under the Proposed Arrangement.

[1]Surgeons in the Surgeon Group also practice at two other hospitals in the region.

[2]The Program Administrator has developed software products that measure cost, quality, and utilization on a national basis. The products are certified by both the American College of Cardiology and the Society of Thoracic Surgery.

B. The Proposed Arrangement

Under the Proposed Arrangement, the Hospital will pay the Surgeon Group a share of the first year cost savings directly attributable to specific changes in the Surgeon Group's operating room practices. The Program Administrator conducted a study of the historic practices at the Hospital's cardiac surgery department and identified twenty-four specific cost-savings opportunities. The results of the Program Administrator's study of the Surgeon Group and the specific cost-savings opportunities are summarized in a "Practice Patterns Report."[3] The Hospital and the Surgeon Group have reviewed the Practice Patterns Report for medical appropriateness and each has adopted its recommendations and conclusions.

In general, the Practice Patterns Report recommends that the Surgeon Group change its current operating room practices to curb the inappropriate use or waste of medical supplies. The Practice Patterns Report identifies twenty-four specific recommendations that can be roughly grouped into the following three categories.

The first category consists of five recommendations that involve limiting the use of certain surgical supplies (hereafter, the "use as needed" recommendations). The Requestors have certified that the individual surgeon will make a patient-by-patient determination as to whether these items are clinically indicated and that the surgical supplies will still be readily available to the surgeons. The Requestors have further certified that any resulting limitations on the use of these products will not adversely affect patient care. Included in this category is a recommendation to limit use of Aprotinin – a medication currently given to many surgical patients pre-operatively to prevent hemorrhaging – to patients that are at higher risk of perioperative hemorrhage as indicated by objective clinical standards.

The second category, involving nine recommendations, consists of the substitution, in whole or in part, of less costly items for the items currently being used by the surgeons. The substitutions involve types of items and services for which a product substitution will have no appreciable clinical significance (e.g., substituting reusable hyperthermia blankets, reusable gel pad, and ace bandages). For example, currently a disposable warming blanket is used on all open heart cases to maintain body temperature. Under the Proposed Arrangement, surgeons would be asked to utilize reusable warming blankets.

The final category, involving ten recommendations, consists of product standardization of certain cardiac devices where medically appropriate. For this category, the Surgeon Group would be required to work in conjunction with the Hospital to evaluate and clinically

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[3]The Practice Patterns Report for the Surgeon Group, dated June 2, 2006, is attached to this advisory opinion as Appendix A. The Requestors' original submission included additional cost savings recommendations that posed an unacceptable risk of fraud and abuse. The Requestors withdrew those recommendations from the Proposed Arrangement.

review vendors and products.[4] The Surgeon Group would agree to use the selected products where medically appropriate, which may require additional training or changes in clinical practice.

The Proposed Arrangement contains several safeguards intended to protect against inappropriate reductions in services. With respect to the use as needed recommendations, the Proposed Arrangement would utilize objective historical and clinical measures reasonably related to the practices and the patient population at the Hospital to establish a "floor" beyond which no savings would accrue to the Surgical Group. For example, with respect to Aprotinin, the Proposed Arrangement uses specific, objective, generally-accepted clinical indicators reasonably related to the practices of the Hospital and its patient population to determine medical appropriateness.[5] Currently, Aprotinin is used in approximately 48% of the cases specified under the Proposed Arrangement. According to the Program Administrator, national data indicates a best practice usage of 20% for Aprotinin. Under the Proposed Arrangement, savings from reduced use of Aprotinin will not be credited to the Surgeon Group if the savings result from utilization of Aprotinin in less than 20% of cases or if the savings result from failure to use Aprotinin in a case that meets the clinical indicators. All surgical cases – including cases in which Aprotinin is not administered – will be reviewed by the Program Administrator to determine if the surgeons followed the objective clinical indicators for determining whether Aprotinin was used appropriately.

With respect to the product substitution recommendations in the Proposed Arrangement, as the identified substitutions[6] will have no appreciable clinical significance, no floors are set.[7]

Importantly, with respect to the product standardization recommendations, the Requestors have certified that the individual surgeons will make a patient-by-patient determination of the most appropriate cardiac device and the availability of the full range of cardiac devices will not be compromised by the product standardization. The Requestors have further

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[4]We note that the Practice Patterns Report identifies with specificity the vendors and products at issue.

[5]The objective clinical indicators used in the Proposed Arrangement to determine when Aprotinin is administered appropriately are cited in medical literature. Lemmer et al., ATS 62: 1659-68 (1996).

[6]The Practice Patterns Report clearly identifies with specificity each substitution recommendation under this category.

[7]We note that for product substitution recommendations that are of clinical significance, we would require additional safeguards, such as the establishment of quality thresholds beyond which no cost savings would be credited.

certified that individual physicians will still have available the same selection of devices after implementation of the Proposed Arrangement as before and that the economies gained through the Proposed Arrangement will result from inherent clinical and fiscal value and not from restricting the availability of devices.

According to the Program Administrator, if implemented in accordance with the Practice Patterns Report's specifications, the twenty-four recommendations would present substantial cost savings opportunities for the Hospital without adversely impacting the quality of patient care.

The Hospital will pay the Surgeon Group 50% of the cost savings achieved by implementing the twenty-four recommendations in the Practice Patterns Report for a period of one year. At the end of the year, cost savings will be calculated separately for each of the twenty-four recommendations; this will preclude shifting of cost savings and ensure that savings generated by utilization beyond the set targets, as applicable, will not be credited to the Surgeon Group. This payment will constitute the entire compensation paid to the Surgeon Group for services performed under the contract memorializing the Proposed Arrangement between the Surgeon Group and the Hospital. For purposes of calculating the payment to the Surgeon Group, the cost savings will be calculated by subtracting the actual costs incurred for the items specified in the twenty-four recommendations when used by surgeons in the Surgeon Group during the specified surgical procedures (the "current year costs"[8]) from the historic costs for the same items when used during comparable surgical procedures in the base year (the "base year costs"[9]). The current year costs will be adjusted to account for any inappropriate reductions in use of items beyond the targets set in the Practice Patterns Report. The payment to the Surgeon Group will be 50% of the difference between the adjusted current year costs and base year costs, if any.

The Hospital will make an aggregate payment to the Surgeon Group, which distributes its profits to each of its members on a per capita basis. Payments to the Surgeon Group will also be subject to the following limitations:

- If the volume of procedures payable by a Federal health care program in the current year exceeds the volume of like procedures payable by a Federal

[8]The current year will be the twelve-month term of the contract for which the Surgeon Group will be compensated under the Proposed Arrangement.

[9]The "base year" will be the twelve months preceding the effective date of the contract. For purposes of this opinion, the Proposed Arrangement is limited to the one-year term of the contract; accordingly, this opinion is without force and effect with respect to any future renewal or extension of the Proposed Arrangement. Notwithstanding, we note that any renewal or extension of the Proposed Arrangement should incorporate updated base year costs.

health care program performed in the base year, there will be no sharing of cost savings for the additional procedures.

- To minimize the surgeons' financial incentive to steer more costly patients to other hospitals, the case severity, ages, and payors of the patient population treated under the Proposed Arrangement will be monitored by a committee composed of representatives of the Requestors, using generally-accepted standards. If there are significant changes from historical measures, the surgeon at issue will be terminated from participation in the Proposed Arrangement.

- The aggregate payment to the Surgeon Group will not exceed 50% of the projected cost savings identified in the Practice Patterns Report.

The Hospital and the Surgeon Group will document the activities and the payment methodology under the Proposed Arrangement and will make the documentation available to the Secretary of the United States Department of Health and Human Services, upon request. In addition, the Hospital and the Surgeon Group will disclose the Proposed Arrangement to the patient, including the fact that the Surgeon Group's compensation is based on a percentage of the Hospital's cost savings. The disclosure will be made to the patient before the patient is admitted to the Hospital for a procedure covered by the Proposed Arrangement; if pre-admission disclosure is impracticable (e.g., the patient is admitted for an unscheduled procedure or the need for the procedure is determined after admission), the disclosure will be made before the patient consents to the surgery. The disclosures will be in writing, and patients will have an opportunity, if desired, to review details of the Proposed Arrangement, including the specific cost savings measures applicable to the patient's surgery.

II. LEGAL ANALYSIS

Arrangements like the Proposed Arrangement are designed to align incentives by offering physicians a portion of a hospital's cost savings in exchange for implementing cost saving strategies. Under the current reimbursement system, the burden of these costs falls on hospitals, not physicians. Payments to physicians based on cost savings may be intended to motivate them to reduce hospital costs associated with procedures performed by physicians at the hospitals.

Properly structured, arrangements that share cost savings can serve legitimate business and medical purposes. Specifically, properly structured arrangements may increase efficiency and reduce waste, thereby potentially increasing a hospital's profitability. However, such arrangements can potentially influence physician judgment to the detriment of patient care. Our concerns include, but are not limited to, the following:
(i) stinting on patient care; (ii) "cherry picking" healthy patients and steering sicker (and more costly) patients to hospitals that do not offer such arrangements; (iii) payments in

exchange for patient referrals; and (iv) unfair competition (a "race to the bottom") among hospitals offering cost savings programs to foster physician loyalty and to attract more referrals.

Hospital cost savings programs in general, and the Proposed Arrangement in particular, may implicate at least three Federal legal authorities: (i) the civil monetary penalty for reductions or limitations of direct patient care services provided to Federal health care program beneficiaries, sections 1128A(b)(1)-(2) of the Act; (ii) the anti-kickback statute, section 1128B(b) of the Act; and (iii) the physician self-referral law, section 1877 of the Act.[10] We address the first two of these authorities; section 1877 of the Act falls outside the scope of the OIG's advisory opinion authority. We express no opinion on the application of section 1877 of the Act to the Proposed Arrangement.

A. The Civil Monetary Penalty, Sections 1128A(b)(1)-(2) of the Act

Sections 1128A(b)(1)-(2) of the Act establish a civil monetary penalty ("CMP") against any hospital or critical access hospital that knowingly makes a payment directly or indirectly to a physician (and any physician that receives such a payment) as an inducement to reduce or limit items or services to Medicare or Medicaid beneficiaries under the physician's direct care. Hospitals that make (and physicians that receive) such payments are liable for CMPs of up to $2,000 per patient covered by the payments. See id. There is no requirement that the prohibited payment be tied to a specific patient or to a reduction in medically necessary care. The CMP applies only to reductions or limitations of items or services provided to Medicare and Medicaid fee-for-service beneficiaries.[11]

The CMP prohibits payments by hospitals to physicians that may induce physicians to reduce or limit items or services furnished to their Medicare and Medicaid patients. A threshold inquiry is whether the Proposed Arrangement will induce physicians to reduce or

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[10]In addition, nonprofit hospital arrangements raise issues of private inurement and private benefit under the Internal Revenue Service's income tax regulations in connection with section 501(c)(3) of the Internal Revenue Code. See Rev. Rul. 69-383, 1969-2 C.B. 113. We express no opinion on the application of the Internal Revenue Code to the Proposed Arrangement.

[11]Physician incentive arrangements related to Medicare risk-based managed care contracts, similar Medicaid contracts, and Medicare Advantage plans (formerly Medicare + Choice) are subject to regulation by the Secretary pursuant to sections 1876(i)(8), 1903(m)(2)(A)(x), and 1852(j)(4) of the Act (respectively), in lieu of being subject to sections 1128A(b)(1)-(2). See OIG letter regarding hospital-physician incentive plans for Medicare and Medicaid beneficiaries enrolled in managed care plans (dated August 19, 1999), available at http://oig.hhs.gov/fraud/docs/alertsandbulletins/gsletter.htm. See also 42 C.F.R. § 417.479 (Medicare HMOs or competitive medical plans); 42 C.F.R. § 422.208 (Medicare Advantage plans); 42 C.F.R. § 438.6 (Medicaid risk plans).

limit items or services. Given the specificity of the Proposed Arrangement, it is possible to review the proposed opportunities for savings individually and evaluate their potential impact on patient care.

Having reviewed the twenty-four individual recommendations, we conclude that, except for the product substitutions (discussed in more detail below), the recommendations implicate the CMP. Simply put, with respect to the recommendations regarding the "use as needed" surgical supplies, Aprotinin, and the product standardization, the Proposed Arrangement constitutes an inducement to reduce or limit the current medical practice at the Hospital. We recognize that the current medical practice may involve care that exceeds the requirements of medical necessity. However, whether the current medical practice reflects necessity or prudence is irrelevant for purposes of the CMP.

With respect to the recommendations regarding specific product substitution recommendations, the identified substitutions will have no appreciable clinical significance; therefore, we believe there will be no perceptible reduction or limitation in the provision of items or services to patients sufficient to trigger the CMP.

In sum, while the recommendations for the specific product substitutions do not run afoul of the CMP, we find that the CMP would apply to the remaining recommendations involving limitations on use of certain surgical supplies, Aprotinin, and product standardization. Notwithstanding, the Proposed Arrangement has several features that, in combination, provide sufficient safeguards so that we would not seek sanctions against the Requestors under sections 1128A(b)(1)-(2) of the Act.

First, the specific cost-saving actions and resulting savings are clearly and separately identified. The transparency of the Proposed Arrangement will allow for public scrutiny and individual physician accountability for any adverse effects of the Proposed Arrangement, including any difference in treatment among patients based on nonclinical indicators. The transparency of the incentives for specific actions and specific procedures will also facilitate accountability through the medical-legal professional liability system.

Second, the Requestors have proffered credible medical support for the position that implementation of the recommendations will not adversely affect patient care. The Proposed Arrangement will be periodically reviewed by the Requestors to confirm that the Proposed Arrangement is not having an adverse impact on clinical care.[12]

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[12]We have had the Proposed Arrangement reviewed by a government medical expert. The medical expert has concluded that the proposed cost savings measures, as described in the advisory opinion request and supplemental submissions, should not adversely affect patient care. For purposes of this opinion, however, we rely solely on the Requestors' certifications and nothing in this advisory opinion should be construed as an endorsement or conclusion as to the medical propriety of the specific activities being undertaken as part of the Proposed Arrangement.

Third, the payments under the Proposed Arrangement are based on all surgeries regardless of the patients' insurance coverage, subject to the cap on payment for Federal health care program procedures. Moreover, the surgical procedures to which the Proposed Arrangement applies are not disproportionately performed on Federal health care program beneficiaries. Additionally, the cost savings are calculated on the Hospital's actual out-of-pocket acquisition costs, not an accounting convention.

Fourth, the Proposed Arrangement protects against inappropriate reductions in services by utilizing objective historical and clinical measures to establish baseline thresholds beyond which no savings accrue to the Surgeon Group. The Requestors have certified that these baseline measures are reasonably related to the Hospital's or comparable hospitals' practices and patient populations. These safeguards are action-specific and not simply based on isolated patient outcome data unrelated to the specific changes in operating room practices.

Fifth, the product standardization portion of the Proposed Arrangement further protects against inappropriate reductions in services by ensuring that individual physicians will still have available the same selection of cardiac devices after implementation of the Proposed Arrangement as before. The Proposed Arrangement is designed to produce savings through inherent clinical and fiscal value and not from restricting the availability of devices.

Sixth, the Hospital and the Surgeon Group will provide written disclosures of their involvement in the Proposed Arrangement to patients whose care may be affected by the Proposed Arrangement and will provide patients an opportunity to review the cost savings recommendations prior to admission to the Hospital (or, where pre-admission consent is impracticable, prior to consenting to surgery). While we do not believe that, standing alone, such disclosures offer sufficient protection from program or patient abuse, effective and meaningful disclosure offers some protection against possible abuses of patient trust.[13]

Seventh, the financial incentives under the Proposed Arrangement are reasonably limited in duration and amount.

Eighth, because the Surgeon Group's profits are distributed to its members on a per capita basis, any incentive for an individual surgeon to generate disproportionate cost savings is mitigated.

Our decision not to impose sanctions on the Requestors in connection with the Proposed Arrangement is an exercise of our discretion and is consistent with our Special Advisory

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[13]Ordinarily, we would expect patient disclosures to be coupled with patient satisfaction surveys that closely monitor patient perceptions of their care. However, in the context of the Proposed Arrangement, which focuses on items used in operating rooms, we believe that patient satisfaction surveys would not be effective.

Bulletin on "Gainsharing Arrangements and CMPs for Hospital Payments to Physicians to Reduce or Limit Services to Beneficiaries" (July 1999) (the "Special Advisory Bulletin"). We reiterate that the CMP applies to any payment by a hospital to a physician that is intended to induce the reduction or limitation of items or services to Medicare or Medicaid patients under the physician's direct clinical care. The Proposed Arrangement is markedly different from many "gainsharing" plans, particularly those that purport to pay physicians a percentage of generalized cost savings not tied to specific, identifiable cost-lowering activities. Importantly, the Proposed Arrangement sets out the specific actions to be taken and ties the remuneration to the actual, verifiable cost savings attributable to those actions. This transparency allows an assessment of the likely effect of the Proposed Arrangement on quality of care and ensures that the identified actions will be the cause of the savings.

Many "gainsharing" plans present substantial risks for both patient and program abuse – risks that are not present in the Proposed Arrangement. Given the limited duration and scope of the Proposed Arrangement, the safeguards provide sufficient protections against patient and program abuse. Other arrangements, including those that are longer in duration or more expansive in scope than the Proposed Arrangement, are likely to require additional or different safeguards.

B. The Anti-Kickback Statute

The anti-kickback statute makes it a criminal offense knowingly and willfully to offer, pay, solicit, or receive any remuneration to induce or reward referrals of items or services reimbursable by a Federal health care program. See section 1128B(b) of the Act. Where remuneration is paid purposefully to induce or reward referrals of items or services payable by a Federal health care program, the anti-kickback statute is violated. By its terms, the statute ascribes criminal liability to parties on both sides of an impermissible "kickback" transaction. For purposes of the anti-kickback statute, "remuneration" includes the transfer of anything of value, directly or indirectly, overtly or covertly, in cash or in kind.

The statute has been interpreted to cover any arrangement where one purpose of the remuneration was to obtain money for the referral of services or to induce further referrals. United States v. Kats, 871 F.2d 105 (9th Cir. 1989); United States v. Greber, 760 F.2d 68 (3d Cir.), cert. denied, 474 U.S. 988 (1985). Violation of the statute constitutes a felony punishable by a maximum fine of $25,000, imprisonment up to five years, or both. Conviction will also lead to automatic exclusion from Federal health care programs, including Medicare and Medicaid. Where a party commits an act described in section 1128B(b) of the Act, the OIG may initiate administrative proceedings to impose civil monetary penalties on such party under section 1128A(a)(7) of the Act. The OIG may also initiate administrative proceedings to exclude such party from the Federal health care programs under section 1128(b)(7) of the Act.

The Department of Health and Human Services has promulgated safe harbor regulations that define practices that are not subject to the anti-kickback statute because such practices would be unlikely to result in fraud or abuse. See 42 C.F.R. § 1001.952. The safe harbors set forth specific conditions that, if met, assure entities involved of not being prosecuted or sanctioned for the arrangement qualifying for the safe harbor. However, safe harbor protection is afforded only to those arrangements that precisely meet all of the conditions set forth in the safe harbor.

The safe harbor for personal services and management contracts, 42 C.F.R. §1001.952(d), is potentially applicable to the Proposed Arrangement. In relevant part for purposes of this advisory opinion, the personal services safe harbor requires that the aggregate compensation paid for the services be set in advance and consistent with fair market value in arm's-length transactions. The Proposed Arrangement would not fit in the safe harbor because the Surgeon Group will be paid on a percentage basis, and thus the compensation would not be set in advance. However, the absence of safe harbor protection is not fatal. Instead, the Proposed Arrangement must be subject to case-by-case evaluation.

Like any compensation arrangement between a hospital and a physician who admits or refers patients to such hospital, we are concerned that the Proposed Arrangement could be used to disguise remuneration from the Hospital to reward or induce referrals by the Surgeon Group. Specifically, the Proposed Arrangement could encourage the surgeons to admit Federal health care program patients to the Hospital, since the surgeons would receive not only their Medicare Part B professional fee, but also, indirectly, a share of the Hospital's payment, depending on cost savings. In other words, the more procedures a surgeon performs at the Hospital, the more money he or she is likely to receive under the Proposed Arrangement.

While we believe the Proposed Arrangement could result in illegal remuneration if the requisite intent to induce referrals were present, we would not impose sanctions in the particular circumstances presented here and as qualified below.

First, the circumstances and safeguards of the Proposed Arrangement reduce the likelihood that the arrangement will be used to attract referring physicians or to increase referrals from existing physicians. Specifically, participation in the Proposed Arrangement will be limited to surgeons already on the medical staff, thus limiting the likelihood that the Proposed Arrangement will attract other surgeons. In addition, the potential savings derived from procedures for Federal health care program beneficiaries will be capped based on the prior year's admissions of Federal health care program beneficiaries. Finally, the contract term will be limited to one year, reducing any incentive to switch facilities, and admissions will be monitored for changes in severity, age, or payor. Thus, while the incentive to refer will not necessarily be eliminated, it will be substantially reduced.

Second, the structure of the Proposed Arrangement eliminates the risk that the Proposed Arrangement will be used to reward cardiologists or other physicians who refer patients to the Surgeon Group or its surgeons. The Surgeon Group is the sole participant in the

Proposed Arrangement and is composed entirely of cardiac surgeons; no cardiologists or other physicians are members of the Surgeon Group or share in its profit distributions. Within the Surgeon Group, profits are distributed to its members on a per capita basis, mitigating any incentive for an individual surgeon to generate disproportionate cost savings.

Third, the Proposed Arrangement sets out with specificity the particular actions that will generate the cost savings on which the payments are based. While many of the recommendations in the Practice Patterns Report are simple common sense, they do represent a change in operating room practice, for which the surgeon is responsible and will have liability exposure. While most of the recommendations would appear to present minimal risk, product standardization, for example, carries some increased liability risk for the physicians. It is not unreasonable for the surgeon to receive compensation for the increased risk from the proposed change in practice. Moreover, the payments will represent a portion of one year's worth of cost savings and will be limited in amount (i.e., the aggregate cap), duration (i.e., the limited contract term), and scope (i.e., the total savings that can be achieved from the implementation of any one recommendation are limited by appropriate utilization levels). The payments under the Proposed Arrangement do not appear unreasonable, given, among other things, the nature of the actions required of the physicians to implement the twenty-four recommended actions, the specificity of the payment formula, and the cap on total remuneration to the Surgeon Group.[14] We caution that payments of 50% of cost savings in other arrangements, including multi-year arrangements or arrangements with generalized cost savings formulae, could well lead to a different result.

In light of these circumstances and safeguards, the Proposed Arrangement poses a low risk of fraud or abuse under the anti-kickback statute.

III. CONCLUSION

Notwithstanding the foregoing, we reiterate our concerns regarding many arrangements between hospitals and physicians to share cost savings. Improperly designed or implemented arrangements risk adversely affecting patient care and could be vehicles to disguise payments for referrals. For example, an arrangement that cannot be adequately and accurately measured for quality of care would pose a high risk of fraud or abuse, as would one that rewards physicians based on overall cost savings without accountability for specific cost reduction measures. Moreover, arrangements structured so as to pose a heightened potential for patient steering and unfair competition would be considered suspect. In short, this opinion is predicated on the specific arrangement posed by the

[14]We are precluded by statute from opining on whether fair market value shall be or was paid for goods, services, or property. See 42 U.S.C. § 1320a-7d(b)(3)(A). While the Requestors have certified that the payments under the Proposed Arrangement are consistent with fair market value, we do not rely on that certification in this opinion, nor have we have made an independent fair market value assessment.

Requestors and is limited to that specific arrangement. Other apparently similar arrangements could raise different concerns and lead to a different result.

Based on the facts certified in your request for an advisory opinion and supplemental submissions, we conclude: (i) the Proposed Arrangement would constitute an improper payment to induce reduction or limitation of services pursuant to sections 1128A(b)(1)-(2) of the Act, but that the OIG would not impose sanctions under sections 1128A(b)(1)-(2) on the Requestors in connection with the Proposed Arrangement; and (ii) the Proposed Arrangement would potentially generate prohibited remuneration under the anti-kickback statute, if the requisite intent to induce or reward referrals of Federal health care program business were present, but that the OIG would not impose administrative sanctions on the Requestors under sections 1128(b)(7) or 1128A(a)(7) of the Act (as those sections relate to the commission of acts described in section 1128B(b) of the Act) in connection with the Proposed Arrangement.

IV. LIMITATIONS

The limitations applicable to this opinion include the following:

- This advisory opinion is issued only to [Names redacted], the requestors of this opinion. This advisory opinion has no application to, and cannot be relied upon by, any other individual or entity.

- This advisory opinion may not be introduced into evidence in any matter involving an entity or individual that is not a requestor to this opinion.

- This advisory opinion is applicable only to the statutory provisions specifically noted above. No opinion is expressed or implied herein with respect to the application of any other Federal, state, or local statute, rule, regulation, ordinance, or other law that may be applicable to the Proposed Arrangement, including, without limitation, the physician self-referral law, section 1877 of the Act.

- This advisory opinion will not bind or obligate any agency other than the U.S. Department of Health and Human Services.

- This advisory opinion is limited in scope to the specific arrangement described in this letter and has no applicability to other arrangements, even those that appear similar in nature or scope.

- No opinion is expressed herein regarding the liability of any party under the False Claims Act or other legal authorities for any improper billing, claims submission, cost reporting, or related conduct.

This opinion is also subject to any additional limitations set forth at 42 C.F.R. Part 1008.

The OIG will not proceed against the Requestors with respect to any action that is part of the Proposed Arrangement taken in good faith reliance upon this advisory opinion, as long as all of the material facts have been fully, completely, and accurately presented, and the Proposed Arrangement in practice comports with the information provided. The OIG reserves the right to reconsider the questions and issues raised in this advisory opinion and, where the public interest requires, to rescind, modify, or terminate this opinion. In the event that this advisory opinion is modified or terminated, the OIG will not proceed against the Requestors with respect to any action taken in good faith reliance upon this advisory opinion, where all of the relevant facts were fully, completely, and accurately presented, and where such action was promptly discontinued upon notification of the modification or termination of this advisory opinion. An advisory opinion may be rescinded only if the relevant and material facts have not been fully, completely, and accurately disclosed to the OIG.

Sincerely,

/s/

Lewis Morris
Chief Counsel to the Inspector General

Attachment A [Redacted]

[*We redact certain identifying information and certain potentially privileged, confidential, or proprietary information associated with the individual or entity, unless otherwise approved by the requestor.*]

Issued: December 28, 2007

Posted: January 14, 2008

[Name and Address Redacted]

Re: OIG Advisory Opinion No. 07-22

Ladies & Gentlemen:

We are writing in response to your request for an advisory opinion concerning an arrangement in which a hospital has agreed to share with a group of anesthesiologists a percentage of the hospital's cost savings arising from the anesthesiologists' implementation of a number of cost reduction measures related to anesthesia services provided during cardiac surgical procedures (the "Arrangement"). The cost savings are measured based on the anesthesiologists' reduction of waste and use of specific devices and supplies during designated cardiac surgery procedures. You have inquired whether the Arrangement constitutes grounds for sanctions arising under: (i) the civil monetary penalty for a hospital's payment to an anesthesiologist to induce reductions or limitations of services to Medicare or Medicaid beneficiaries under the anesthesiologist's direct care, sections 1128A(b)(1)-(2) of the Social Security Act (the "Act"); or (ii) the exclusion authority at section 1128(b)(7) of the Act or the civil monetary penalty provision at section 1128A(a)(7) of the Act, as those sections relate to the commission of acts described in section 1128B(b) of the Act, the anti-kickback statute.

You have certified that all of the information provided in your request, including all supplementary letters, is true and correct and constitutes a complete description of the relevant facts and agreements among the parties.

In issuing this opinion, we have relied solely on the facts and information presented to us. We have not undertaken an independent investigation of such information. This opinion is limited to the facts presented. If material facts have not been disclosed or have been misrepresented, this opinion is without force and effect.

Based on the information provided and the totality of the facts as described and certified in your request for an advisory opinion and supplemental submissions, we conclude that: (i) the Arrangement could constitute an improper payment to induce reduction or limitation of services pursuant to sections 1128A(b)(1)-(2) of the Act, but that the Office of Inspector General ("OIG") would not impose sanctions on the requestors of this advisory opinion, [names redacted] (collectively, the "Requestors"), in connection with the Arrangement; and (ii) the Arrangement could potentially generate prohibited remuneration under the anti-kickback statute, if the requisite intent to induce or reward referrals of Federal health care program business were present, but that the OIG would not impose administrative sanctions on the Requestors under sections 1128(b)(7) or 1128A(a)(7) of the Act (as those sections relate to the commission of acts described in section 1128B(b) of the Act) in connection with the Arrangement.

This opinion may not be relied on by any persons other than the Requestors and is further qualified as set out in Part IV below and in 42 C.F.R. Part 1008.

I. FACTUAL BACKGROUND

A. Parties

The Hospital. [Name redacted] (the "Hospital") is an acute care hospital in [city and state redacted], that offers a broad range of inpatient and outpatient hospital services, including cardiac surgery services. The Hospital is a participating provider in the Medicare and Medicaid programs.

The Anesthesiology Group. [Name redacted] (the "Anesthesiology Group") is a professional corporation comprised only of anesthesiologists who are licensed in [state redacted], have active medical staff privileges at the Hospital, and whose practice includes the provision of cardiac anesthesia services. The Anesthesiology Group is the only group administering cardiac anesthesia at the Hospital. The Anesthesiology Group's practice is limited to the administration of anesthesia ancillary to procedures performed by other physicians. It does not furnish pain management or similar free-standing professional services or order or furnish any separately billable Hospital services. The Anesthesia Group bills and collects its own professional fees; it does not reassign such fees to the Hospital.

The Program Administrator. The Hospital engaged [name redacted] (the "Program Administrator") to administer the Arrangement. The Program Administrator collected data

and analyzed and managed the Arrangement.[1] The Hospital paid the Program Administrator a monthly fixed fee certified by the Requestors to be fair market value in an arm's-length transaction for services provided by the Program Administrator under the Arrangement. The fee was not tied in any way to cost savings or the Anesthesiology Group's compensation under the Arrangement.

B. The Arrangement

Under the Arrangement, the Hospital agreed to pay the Anesthesiology Group a share of cost savings directly attributable to specific changes in the Anesthesiology Group's anesthesia practices. The Requestors implemented the Arrangement – and the Anesthesiology Group began performance of the specific changes in operating room practices – prior to requesting this advisory opinion. However, the Hospital has not paid amounts owed to the Anesthesiology Group under the Arrangement pending the outcome of this opinion.[2] Thus, we are treating the Arrangement as an existing arrangement for purposes of this advisory opinion. The Requestors have certified that the Hospital will make payments owed under the Arrangement upon receipt of a favorable advisory opinion.

The Program Administrator conducted a study of the historic anesthesia practices at the Hospital's cardiac surgery department and identified five specific cost-savings opportunities. The results of the Program Administrator's study of the Anesthesiology Group and the specific cost-savings opportunities are summarized in a document entitled "Executive Summary of Value Share for Cardiac Anesthesia" (the "Executive Summary").[3] The Hospital and the Anesthesiology Group reviewed the recommendations and conclusions outlined in the Executive Summary for medical appropriateness, and each adopted them.

In general, the Executive Summary recommended that the Anesthesiology Group change its operating room practices to curb the inappropriate use or waste of medical supplies. The

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[1]The Program Administrator has developed software products that measure cost, quality, and utilization on a national basis. The products are certified by both the American College of Cardiology and the Society of Thoracic Surgery.

[2]Nonpayment of amounts owed pursuant to a contractual agreement does not, by itself, absolve parties from liability under the fraud and abuse laws.

[3]The Executive Summary for the Anesthesiology Group is attached to this advisory opinion as Appendix A. This opinion is based on the specific cost savings recommendations and associated facts set forth in the Executive Summary. Similar cost savings recommendations involving different facts could produce a different result.

Executive Summary identified five specific recommendations that can be roughly grouped into the following three categories.

- "*Use as Needed" Items*. The Anesthesiology Group was to eliminate the routine use in the specific cardiac procedures covered by the Arrangement of (i) a specific drug and (ii) a device used to monitor patients' brain function (when the reduction occured in conjunction with compensating changes in clinical practice) (hereafter, the "use as needed" recommendations).[4] The Requestors have certified that the individual anesthesiologists made patient-by-patient determinations as to whether the items were clinically indicated in particular procedures and that the items remained readily available to the anesthesiologists. The Requestors further certified that any change in the use of these items did not adversely affect patient care.[5]

- *Product Substitution*. The Anesthesiology Group was to substitute, in whole or in part, less costly items for items currently being used by the anesthesiologists during the covered cardiac procedures (hereafter, the "product substitution" recommendations). Specifically, one recommendation involved the use of a specific catheter, and the other involved a nasogastric tube made with a less expensive material.

- *Product Standardization*. The Anesthesiology Group was to standardize the use of certain fluid warming hot lines where medically appropriate. For this category, the Anesthesiology Group was required to work with the Hospital to evaluate and clinically review vendors and products.[6] The Anesthesiology Group agreed to use the selected product where medically appropriate, which might have required additional training or changes in clinical practice.

The Arrangement contained several safeguards intended to protect against inappropriate reductions in services. The Executive Summary clearly identified with specificity each "use as needed" and product substitution recommendation. For the catheter substitution recommendation, the Arrangement used objective historical and clinical measures

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[4]The Executive Summary identified with specificity the products at issue.

[5]In the case of the device, the Requestors indicate its use in the covered procedures is not supported by medical literature and that the American Society of Anesthesiology has issued a practice advisory stating that its routine use is not indicated. With respect to the drug, the Requestors indicate that its routine use is not supported by evidence and that its use significantly increases costs without proven increases in benefits.

[6]The Executive Summary identified with specificity the type of product at issue.

reasonably related to the practices and the patient population at the Hospital, and, in some cases, data at comparable hospitals to establish thresholds beyond which no savings accrued to the Anesthesiology Group. The Executive Summary indicated that a less expensive catheter could appropriately be used in 90% of cases; accordingly, the savings achievable by using less expensive catheters was limited to 90% of cases. The Anesthesiology Group will receive no share of cost savings attributable to using less expensive catheters in more than 90% of cases.[7]

Further, the Program Administrator tracked and measured the Hospital's performance of the covered cardiac procedures against the quality indicators established by the Society of Thoracic Surgeons ("STS") throughout the base year and contract year (as defined below). According to the Requestors, the STS quality indicators against which all of the Arrangement's recommendations were evaluated reflect objective hospital baselines and incorporate specificity sufficient to correlate outcomes with operating room practices. The indicators are action-specific and not simply based on isolated patient outcome data unrelated to specific changes in operating room practices. No cost sharing amounts were allocated to the Anesthesiology Group for procedures involving reductions in historical STS quality indicators.

Importantly, with respect to the recommendation to standardize fluid warming hot lines, the Requestors have certified that the individual anesthesiologists made patient-by-patient determinations of the most appropriate fluid warming hot lines, and the availability of the full range of lines was not compromised by the product standardization. The Requestors have further certified that individual anesthesiologists still had available the same selection of lines after implementation of the Arrangement as before and that the economies gained through the Arrangement resulted from inherent clinical and fiscal value and not from restricting the availability of warming hot lines.

Finally, the Requestors have certified that all items covered by the Arrangement remained readily available for use by the anesthesiologists after implementation of the Arrangement.

According to the Program Administrator, to the extent implemented in accordance with the Executive Summary's specifications, the five recommendations presented substantial cost

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[7]The Arrangement did not include comparable objective utilization thresholds for recommendations to eliminate use of the brain function monitor and to use a nasogastric tube made of a less expensive material in the covered cardiac procedures. The Requestors have certified that the former recommendation was consistent with a practice advisory issued by the American Society of Anesthesiology and that the latter recommendation was consistent with the routine standard of care for the covered procedures.

savings opportunities for the Hospital without any adverse impact on the quality of patient care.

The Hospital intends to pay the Anesthesiology Group 50% of the cost savings achieved by implementing the five recommendations in the Executive Summary for a period of one year. At the end of the applicable year (the "contract year"), cost savings were calculated separately for each of the five recommendations; this precluded shifting of cost savings and ensured that savings generated by utilization reduced below the set targets, as applicable, were not credited to the Anesthesiology Group. The payment, when made, will constitute the entire compensation paid to the Anesthesiology Group for services performed pursuant to the contract memorializing the Arrangement between the Anesthesiology Group and the Hospital. For purposes of calculating the payment to the Anesthesiology Group, the cost savings were calculated by subtracting the actual costs incurred during the contract year for the items specified in the five recommendations when used by anesthesiologists in the Anesthesiology Group during the specified surgical procedures (the "contract year costs"[8]) from the historic costs for the same items when used during comparable surgical procedures in the base year (the "base year costs"[9]). The current year costs were adjusted to account for any inappropriate reductions in use of items beyond the targets set in the Executive Summary or in connection with reductions in the STS quality indicators. The payment to the Anesthesiology Group was calculated to be 50% of the difference between the adjusted contract year costs and base year costs.

The Hospital is obligated to make an aggregate payment to the Anesthesiology Group, which distributes its profits to each of its members on a per capita basis. Calculation of the payments to the Anesthesiology Group was also subject to the following limitations:

- If the Anesthesiology Group's volume of procedures payable by a Federal health care program in the contract year exceeded the volume of like procedures payable by a Federal health care program performed in the base year, there was no sharing of cost savings for the additional procedures.

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[8]The current year was the twelve-month period for which the Anesthesiology Group is to be compensated under the Arrangement.

[9]The "base year" will be the twelve months preceding the current year of the arrangement. For purposes of this opinion, the Arrangement is limited to a one-year term; accordingly, this opinion is without force and effect with respect to any future renewal or extension of the Arrangement. Notwithstanding, we note that any renewal or extension of the Arrangement should incorporate updated base year costs.

- To minimize the potential for steering of more costly patients to other hospitals, the case severity, ages, and payors of the patient population treated under the Arrangement were monitored by a committee composed of representatives of the Requestors, using generally-accepted standards. If significant changes from historical measures indicated that a physician had altered his or her referral patterns in a manner beneficial to the Hospital as a result of the Arrangement, the physician at issue would have been terminated from participation in the Arrangement. No physicians were terminated.

- The Executive Summary identified projected cost savings, and the aggregate payment to the Anesthesiology Group, when made, will not exceed 50% of those amounts.

The Hospital and the Anesthesiology Group documented the activities and the payment methodology under the Arrangement and agreed to make the documentation available to the Secretary of the United States Department of Health and Human Services, upon request. In addition, the Hospital and the Anesthesiology Group disclosed the Arrangement to patients, including the fact that the Anesthesiology Group's compensation was based on a percentage of the Hospital's cost savings. The disclosure was made to the patient before the patient was admitted to the Hospital for a procedure covered by the Arrangement; if pre-admission disclosure was impracticable (e.g., the patient was admitted for an unscheduled procedure or the need for the procedure was determined after admission), the disclosure was made before the patient consented to the surgery. The disclosures were in writing, and patients had an opportunity, if desired, to review details of the Arrangement, including the specific cost savings measures applicable to the patient's surgery.

II. LEGAL ANALYSIS

Arrangements like the Arrangement are designed to align incentives by offering physicians a portion of a hospital's cost savings in exchange for implementing cost saving strategies. Under the current reimbursement system, the burden of these costs falls on hospitals, not physicians. Payments to physicians based on cost savings may be intended to motivate them to reduce hospital costs associated with procedures performed at the hospital.

Properly structured, arrangements that share cost savings can serve legitimate business and medical purposes. Specifically, properly structured arrangements may increase efficiency and reduce waste, thereby potentially increasing a hospital's profitability. However, such arrangements can potentially influence physicians' judgment to the detriment of patient care. Our concerns include, but are not limited to, the following: (i) stinting on patient care; (ii) "cherry picking" healthy patients and steering sicker (and more costly) patients to hospitals that do not offer such arrangements; (iii) payments in exchange for patient

referrals; and (iv) unfair competition (a "race to the bottom") among hospitals offering cost savings programs to foster physician loyalty and to attract more referrals.

Hospital cost savings programs in general, and the Arrangement in particular, may implicate at least three Federal legal authorities: (i) the civil monetary penalty for reductions or limitations of direct patient care services provided to Federal health care program beneficiaries, sections 1128A(b)(1)-(2) of the Act; (ii) the anti-kickback statute, section 1128B(b) of the Act; and (iii) the physician self-referral law, section 1877 of the Act.[10] We address the first two of these authorities; section 1877 of the Act falls outside the scope of the OIG's advisory opinion authority. We express no opinion on the application of section 1877 of the Act to the Arrangement.

A. The Civil Monetary Penalty, Sections 1128A(b)(1)-(2) of the Act

Sections 1128A(b)(1)-(2) of the Act establish a civil monetary penalty ("CMP") against any hospital or critical access hospital that knowingly makes a payment directly or indirectly to a physician (and any physician that receives such a payment) as an inducement to reduce or limit items or services to Medicare or Medicaid beneficiaries under the physician's direct care. Hospitals that make (and physicians that receive) such payments are liable for CMPs of up to $2,000 per patient covered by the payments. See id. There is no requirement that the prohibited payment be tied to a specific patient or to a reduction in medically necessary care. The CMP applies only to reductions or limitations of items or services provided to Medicare and Medicaid fee-for-service beneficiaries.[11]

The CMP prohibits payments by hospitals to physicians that may induce physicians to reduce or limit items or services furnished to their Medicare and Medicaid patients. A

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[10]In addition, nonprofit hospital arrangements raise issues of private inurement and private benefit under the Internal Revenue Service's income tax regulations in connection with section 501(c)(3) of the Internal Revenue Code. See Rev. Rul. 69-383, 1969-2 C.B. 113. We express no opinion on the application of the Internal Revenue Code to the Arrangement.

[11]Physician incentive arrangements related to Medicare risk-based managed care contracts, similar Medicaid contracts, and Medicare Advantage plans (formerly Medicare + Choice) are subject to regulation by the Secretary pursuant to sections 1876(i)(8), 1903(m)(2)(A)(x), and 1852(j)(4) of the Act (respectively), in lieu of being subject to sections 1128A(b)(1)-(2). See OIG letter regarding hospital-physician incentive plans for Medicare and Medicaid beneficiaries enrolled in managed care plans (dated August 19, 1999), available at http://oig.hhs.gov/fraud/docs/alertsandbulletins/gsletter.htm. See also 42 C.F.R. § 417.479 (Medicare HMOs or competitive medical plans); 42 C.F.R. § 422.208 (Medicare Advantage plans); 42 C.F.R. § 438.6 (Medicaid risk plans).

threshold inquiry is whether the Arrangement might have induced the anesthesiologists in the Anesthesiology Group to reduce or limit items or services. Given the specificity of the Arrangement, it is possible to review the opportunities for savings individually and evaluate their potential impact on patient care.

Having reviewed the five individual recommendations, we conclude that the recommendations implicated the CMP. Simply put, the Arrangement might have induced physicians to reduce or limit the then-current medical practice at the Hospital. We recognize that the then-current medical practice may have involved care that exceeded the requirements of medical necessity. However, whether current medical practice reflects necessity or prudence is irrelevant for purposes of the CMP.

Notwithstanding, the Arrangement has several features that, in combination, provide sufficient safeguards so that we would not seek sanctions against the Requestors under sections 1128A(b)(1)-(2) of the Act.

First, the specific cost-saving actions and resulting savings were clearly and separately identified. The transparency of the Arrangement allowed, and will continue to allow, for public scrutiny and individual physician accountability for any adverse effects of the Arrangement, including any difference in treatment among patients based on nonclinical indicators. The transparency of the incentives for specific actions and specific procedures also facilitates accountability through the medical-legal professional liability system.

Second, the Requestors have proffered credible medical support for the position that implementation of the recommendations did not adversely affect patient care. The Arrangement was periodically reviewed by the Requestors to confirm that the Arrangement was not having an adverse impact on clinical care.[12]

Third, the amount to be paid under the Arrangement has been calcuated based on all surgeries regardless of the patients' insurance coverage, subject to the cap on payment for Federal health care program procedures. Moreover, the surgical procedures to which the Arrangement applied were not disproportionately performed on Federal health care program

[12]We have had the Arrangement reviewed by an independent medical expert. The medical expert concluded that the cost savings measures, as described in the advisory opinion request and supplemental submissions, should not adversely affect patient care. For purposes of this opinion, however, we rely solely on the Requestors' certifications and nothing in this advisory opinion should be construed as an endorsement or conclusion as to the medical propriety of the specific activities undertaken as part of the Arrangement.

beneficiaries. Additionally, the cost savings have been calculated on the Hospital's actual out-of-pocket acquisition costs, not an accounting convention.

Fourth, the Arrangement protected against inappropriate reductions in services by utilizing objective historical and clinical measures to establish baseline thresholds beyond which no savings accrued to the Anesthesiology Group. The Requestors have certified that the baseline measure establishing a "floor" for reduced use of the particular catheter was reasonably related to the Hospital's or comparable hospitals' practices and patient populations, and that the STS quality indicators against which all of the Arrangement's recommendations were evaluated reflect objective hospital baselines and incorporate specificity sufficient to correlate outcomes with operating room practices; the indicators are action-specific and not simply based on isolated patient outcome data unrelated to specific changes in operating room practices. No cost sharing amounts were allocated to the Anesthesiology Group where there were reductions in historical STS quality indicators.

Fifth, the product standardization recommendation protected against inappropriate reductions in services by ensuring that individual anesthesiologists still had available the same selection of fluid warming hot lines after implementation of the Arrangement as before. The Arrangement was designed to produce savings through inherent clinical and fiscal value and not from restricting the availability of devices.

Sixth, the Hospital and the Anesthesiology Group provided written disclosures of their involvement in the Arrangement to patients whose care may have been affected by the Arrangement and provided patients an opportunity to review the cost savings recommendations prior to admission to the Hospital (or, where pre-admission consent was impracticable, prior to consenting to surgery). While we do not believe that, standing alone, such disclosures offer sufficient protection from program or patient abuse, effective and meaningful disclosure offers some protection against possible abuses of patient trust.[13]

Seventh, the financial incentives under the Arrangement were reasonably limited in duration and amount.

Eighth, because the Anesthesiology Group distributes profits to its members on a per capita basis, any incentive for an individual anesthesiologist to generate disproportionate cost savings is mitigated.

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[13]Ordinarily, we would expect patient disclosures to be coupled with patient satisfaction surveys that closely monitor patient perceptions of their care. However, in the context of the Arrangement, which focuses on items used in operating rooms, we believe that patient satisfaction surveys would not be effective.

Our decision not to impose sanctions on the Requestors in connection with the Arrangement is an exercise of our discretion and is consistent with our Special Advisory Bulletin on "Gainsharing Arrangements and CMPs for Hospital Payments to Physicians to Reduce or Limit Services to Beneficiaries" (July 1999) (the "Special Advisory Bulletin"). We reiterate that the CMP applies to any payment by a hospital to a physician that is intended to induce the reduction or limitation of items or services to Medicare or Medicaid patients under the physician's direct clinical care. The Arrangement is markedly different from "gainsharing" plans that purport to pay physicians a percentage of generalized cost savings not tied to specific, identifiable cost-lowering activities. Importantly, the Arrangement set out the specific actions to be taken and tied the remuneration to the actual, verifiable cost savings attributable to those actions. This transparency allowed an assessment of the likely effect of the Arrangement on quality of care and ensured that the identified actions caused the savings.

"Gainsharing" plans can present substantial risks for both patient and program abuse – risks that are not present in the Arrangement. Given the limited duration and scope of the Arrangement, the safeguards provide sufficient protections against patient and program abuse. Other arrangements, including those that are more expansive in scope or less specific than the Arrangement, are likely to require additional or different safeguards.

B. The Anti-Kickback Statute

The anti-kickback statute makes it a criminal offense knowingly and willfully to offer, pay, solicit, or receive any remuneration to induce or reward referrals of items or services reimbursable by a Federal health care program. See section 1128B(b) of the Act. Where remuneration is paid purposefully to induce or reward referrals of items or services payable by a Federal health care program, the anti-kickback statute is violated. By its terms, the statute ascribes criminal liability to parties on both sides of an impermissible "kickback" transaction. For purposes of the anti-kickback statute, "remuneration" includes the transfer of anything of value, directly or indirectly, overtly or covertly, in cash or in kind.

The statute has been interpreted to cover any arrangement where one purpose of the remuneration was to obtain money for the referral of services or to induce further referrals. United States v. Kats, 871 F.2d 105 (9th Cir. 1989); United States v. Greber, 760 F.2d 68 (3d Cir.), cert. denied, 474 U.S. 988 (1985). Violation of the statute constitutes a felony punishable by a maximum fine of $25,000, imprisonment up to five years, or both. Conviction will also lead to automatic exclusion from Federal health care programs, including Medicare and Medicaid. Where a party commits an act described in section 1128B(b) of the Act, the OIG may initiate administrative proceedings to impose civil monetary penalties on such party under section 1128A(a)(7) of the Act. The OIG may also

initiate administrative proceedings to exclude such party from the Federal health care programs under section 1128(b)(7) of the Act.

The Department of Health and Human Services has promulgated safe harbor regulations that define practices that are not subject to the anti-kickback statute because such practices would be unlikely to result in fraud or abuse. See 42 C.F.R. § 1001.952. The safe harbors set forth specific conditions that, if met, assure entities involved of not being prosecuted or sanctioned for the arrangement qualifying for the safe harbor. However, safe harbor protection is afforded only to those arrangements that precisely meet all of the conditions set forth in the safe harbor.

The safe harbor for personal services and management contracts, 42 C.F.R. §1001.952(d), is potentially applicable to the Arrangement. In relevant part for purposes of this advisory opinion, the personal services safe harbor requires that the aggregate compensation paid for the services be set in advance and consistent with fair market value in arm's-length transactions. The Arrangement can not fit in the safe harbor because the payment owed to the Anesthesiology Group was calculated on a percentage basis, and thus the aggregate compensation was not set in advance. However, the absence of safe harbor protection is not fatal. Instead, the Arrangement must be subject to case-by-case evaluation.

As with any compensation arrangement between a hospital and a physician potentially in a position to generate business, directly or indirectly, for the hospital, we are concerned that the Arrangement could have been used to disguise remuneration from the Hospital to the Anesthesiology Group or its anesthesiologists. Under the Arrangement, the anesthesiologists would receive not only their professional fees, but also, indirectly, a share of the Hospital's payment, depending on cost savings. In other words, the more anesthesia services an anesthesiologist furnishes at the Hospital, the more money he or she is likely to receive under the Arrangement. Thus, the Arrangement will generate remuneration for the anesthesiologists.

Typically, anesthesiologists are less likely to generate business for hospitals than many other types of physicians, although some anesthesiologists perform procedures themselves (e.g., pain management procedures), order additional items or services for existing patients, or otherwise generate Federally payable business for hospitals. Thus, depending on the facts, anesthesiologists may be in a position, directly or indirectly, to generate Federal health care program business, and purposeful payments to induce such business would run afoul of the statute. Here, it appears unlikely that the anesthesiologists in the Anesthesiology Group are in a position to generate Federal health care program business for the Hospital. The nature of the specific services furnished by the Anesthesiology Group at the Hospital, as well as the nature of the relationship between the parties (including the fact that the anesthesiologists do not reassign their right to payment to the Hospital),

substantially limit the opportunities for the Anesthesiology Group to generate Federal health care program business for the Hospital.[14]

The structure of the Arrangement adequately addresses any residual risk of improper referral payments.

First, participation in the Arrangement was limited to anesthesiologists already on the medical staff, thus limiting the likelihood that the Arrangement would have attracted other anesthesiologists to the Hospital. In addition, the potential savings derived from procedures for Federal health care program beneficiaries were capped based on the prior year's admissions of Federal health care program beneficiaries. Finally, the contract year for which payments were calculated was limited to one year, reducing any incentive for anesthesiologists to switch facilities to earn cost sharing payments, and patient admissions were monitored for changes in severity, age, or payor to ensure that the Arrangement did not result in inappropriate changes in referral patterns. Thus, while the incentive to generate business was not necessarily eliminated, it was substantially reduced.

Second, the structure of the Arrangement eliminated the risk that the Arrangement was used to reward physicians who referred patients to, or otherwise generated business for, the Hospital, the Anesthesiology Group, or its anesthesiologists. The Anesthesiology Group is the sole participant in the Arrangement and is composed entirely of anesthesiologists; no cardiologists, cardiac surgeons, or other physicians are members of the Anesthesiology Group or share in its profit distributions. Within the Anesthesiology Group, profits are distributed to its members on a per capita basis, mitigating any incentive for an individual anesthesiologist to generate disproportionate cost savings.

Third, the Arrangement set out with specificity the particular actions that generated the cost savings on which the payments were based. The recommendations in the Executive Summary represented a change in operating room practice, for which the anesthesiologist was responsible and had liability exposure. It is not unreasonable for the anesthesiologist to receive compensation for the increased risk from the changes in practice. Moreover, the payments to be made represent a portion of one year's worth of cost savings and are limited in amount (i.e., the aggregate cap), duration (i.e., the limited term), and scope (i.e., the total savings that can be achieved from the implementation of any one recommendation were limited by appropriate utilization levels). The payments under the Arrangement do not appear unreasonable, given, among other things, the nature of the actions required of the

[14]Moreover, we note that the typical anti-kickback concern about arrangements between hospitals and anesthesiologists is the risk of remuneration flowing from the anesthesiologists to the hospital in return for hospital business.

anesthesiologists to implement the five recommended actions, the specificity of the payment formula, and the cap on total remuneration to the Anesthesiology Group.[15] We caution that payments of 50% of cost savings in other arrangements, including multi-year arrangements or arrangements with generalized cost savings formulae, could well lead to a different result.

In light of these circumstances and safeguards, the Arrangement poses a low risk of fraud or abuse under the anti-kickback statute.

III. CONCLUSION

Notwithstanding the foregoing, we reiterate our concerns regarding many arrangements between hospitals and physicians to share cost savings. Improperly designed or implemented arrangements risk adversely affecting patient care and could be vehicles to disguise payments for referrals. For example, an arrangement that cannot be adequately and accurately measured for quality of care would pose a high risk of fraud or abuse, as would one that rewards physicians based on overall cost savings without accountability for specific cost reduction measures. Moreover, arrangements structured so as to pose a heightened potential for patient steering and unfair competition would be considered suspect. In short, this opinion is predicated on the specific arrangement posed by the Requestors and is limited to that specific arrangement. Other apparently similar arrangements could raise different concerns and lead to a different result.

Based on the facts certified in your request for an advisory opinion and supplemental submissions, we conclude: (i) the Arrangement could constitute an improper payment to induce reduction or limitation of services pursuant to sections 1128A(b)(1)-(2) of the Act, but that the OIG would not impose sanctions under sections 1128A(b)(1)-(2) on the Requestors in connection with the Arrangement; and (ii) the Arrangement could potentially generate prohibited remuneration under the anti-kickback statute, if the requisite intent to induce or reward referrals of Federal health care program business were present, but that the OIG would not impose administrative sanctions on the Requestors under sections 1128(b)(7) or 1128A(a)(7) of the Act (as those sections relate to the commission of acts described in section 1128B(b) of the Act) in connection with the Arrangement.

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[15]We are precluded by statute from opining on whether fair market value shall be or was paid for goods, services, or property. See 42 U.S.C. § 1320a-7d(b)(3)(A). While the Requestors have certified that the payments under the Arrangement are consistent with fair market value, we do not rely on that certification in this opinion, nor have we made an independent fair market value assessment.

IV. LIMITATIONS

The limitations applicable to this opinion include the following:

- This advisory opinion is issued only to [names redacted], the requestors of this opinion. This advisory opinion has no application to, and cannot be relied upon by, any other individual or entity.

- This advisory opinion may not be introduced into evidence in any matter involving an entity or individual that is not a requestor to this opinion.

- This advisory opinion is applicable only to the statutory provisions specifically noted above. No opinion is expressed or implied herein with respect to the application of any other Federal, state, or local statute, rule, regulation, ordinance, or other law that may be applicable to the Arrangement, including, without limitation, the physician self-referral law, section 1877 of the Act.

- This advisory opinion will not bind or obligate any agency other than the U.S. Department of Health and Human Services.

- This advisory opinion is limited in scope to the specific arrangement described in this letter and has no applicability to other arrangements, even those that appear similar in nature or scope.

- No opinion is expressed herein regarding the liability of any party under the False Claims Act or other legal authorities for any improper billing, claims submission, cost reporting, or related conduct.

This opinion is also subject to any additional limitations set forth at 42 C.F.R. Part 1008.

The OIG will not proceed against the Requestors with respect to any action that is part of the Arrangement taken in good faith reliance upon this advisory opinion, as long as all of the material facts have been fully, completely, and accurately presented, and the Arrangement in practice comports with the information provided. The OIG reserves the right to reconsider the questions and issues raised in this advisory opinion and, where the public interest requires, to rescind, modify, or terminate this opinion. In the event that this advisory opinion is modified or terminated, the OIG will not proceed against the Requestors with respect to any action taken in good faith reliance upon this advisory opinion, where all of the relevant facts were fully, completely, and accurately presented, and where such action was promptly discontinued upon notification of the modification or termination of this

advisory opinion. An advisory opinion may be rescinded only if the relevant and material facts have not been fully, completely, and accurately disclosed to the OIG.

Sincerely,

/s/

Lewis Morris
Chief Counsel to the Inspector General

[Appendix A redacted]

[*We redact certain identifying information and certain potentially privileged, confidential, or proprietary information associated with the individual or entity, unless otherwise approved by the requestor.*]

Issued: December 28, 2007

Posted: January 14, 2008

[Name and address redacted]

Re: OIG Advisory Opinion No. 07-21

Ladies & Gentlemen:

We are writing in response to your request for an advisory opinion concerning an arrangement in which a hospital has agreed to share with a group of cardiac surgeons a percentage of the hospital's cost savings arising from the surgeons' implementation of a number of cost reduction measures in certain surgical procedures (the "Arrangement"). The cost savings are measured based on the surgeons' reduction of waste and use of specific supplies during designated cardiac surgery procedures. You have inquired whether the Arrangement constitutes grounds for sanctions arising under: (i) the civil monetary penalty for a hospital's payment to a physician to induce reductions or limitations of services to Medicare or Medicaid beneficiaries under the physician's direct care, sections 1128A(b)(1)-(2) of the Social Security Act (the "Act"); or (ii) the exclusion authority at section 1128(b)(7) of the Act or the civil monetary penalty provision at section 1128A(a)(7) of the Act, as those sections relate to the commission of acts described in section 1128B(b) of the Act, the anti-kickback statute.

You have certified that all of the information provided in your request, including all supplementary letters, is true and correct and constitutes a complete description of the relevant facts and agreements among the parties.

In issuing this opinion, we have relied solely on the facts and information presented to us. We have not undertaken an independent investigation of such information. This opinion is

limited to the facts presented. If material facts have not been disclosed or have been misrepresented, this opinion is without force and effect.

Based on the information provided and the totality of the facts as described and certified in your request for an advisory opinion and supplemental submissions, we conclude that: (i) the Arrangement could constitute an improper payment to induce reduction or limitation of services pursuant to sections 1128A(b)(1)-(2) of the Act, but that the Office of Inspector General ("OIG") would not impose sanctions on the requestors of this advisory opinion, [names redacted] (collectively, the "Requestors"), in connection with the Arrangement; and (ii) the Arrangement could potentially generate prohibited remuneration under the anti-kickback statute, if the requisite intent to induce or reward referrals of Federal health care program business were present, but that the OIG would not impose administrative sanctions on the Requestors under sections 1128(b)(7) or 1128A(a)(7) of the Act (as those sections relate to the commission of acts described in section 1128B(b) of the Act) in connection with the Arrangement.

This opinion may not be relied on by any persons other than the Requestors and is further qualified as set out in Part IV below and in 42 C.F.R. Part 1008.

I. FACTUAL BACKGROUND

A. Parties

The Hospital. [Name redacted] (the "Hospital") is an acute care hospital in [city and state redacted], that offers a broad range of inpatient and outpatient hospital services, including cardiac surgery services. The Hospital is a participating provider in the Medicare and Medicaid programs.

The Surgical Group. [Name redacted] (the "Surgical Group") is a limited liability company comprised only of cardiac surgeons who are licensed in [state redacted] and have active medical staff privileges at the Hospital. The cardiac surgeons refer patients to the Hospital for inpatient and outpatient hospital services. The Surgical Group is the only group of cardiac surgeons that practices at the Hospital and performs 100% of the Hospital's cardiac surgery.

The Program Administrator. The Hospital engaged [name redacted] (the "Program Administrator") to administer the Arrangement. The Program Administrator collected data

and analyzed and manages the Arrangement.[1] The Hospital paid the Program Administrator a monthly fixed fee certified by the Requestors to be fair market value in an arm's-length transaction for services provided by the Program Administrator under the Arrangement. The fee was not tied in any way to cost savings or the Surgical Group's compensation under the Arrangement.

B. The Arrangement

Under the Arrangement, the Hospital agreed to pay the Surgical Group a share of cost savings directly attributable to specific changes in the Surgical Group's operating room practices. The Requestors implemented the Arrangement – and the Surgical Group began performance of the specific changes in operating room practices – prior to requesting this advisory opinion. However, the Hospital has not paid amounts owed to the Surgical Group under the Arrangement pending the outcome of this opinion.[2] Thus, we are treating the Arrangement as an existing arrangement for purposes of this advisory opinion. The Requestors have certified that the Hospital will make payments owed under the Arrangement upon receipt of a favorable advisory opinion.

To develop the Arrangement, the Program Administrator conducted a study of the historic practices at the Hospital's cardiac surgery department and identified twenty-five specific cost-savings opportunities. The Program Administrator summarized the results of the study of the Surgical Group and the specific cost-savings opportunities in a document entitled [title redacted] (the "Executive Summary").[3] The Hospital and the Surgical Group reviewed the Executive Summary for medical appropriateness, and each adopted its recommendations and conclusions.

In general, the Executive Summary recommended that the Surgical Group change its operating room practices to curb the inappropriate use or waste of medical supplies. The

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[1]The Program Administrator has developed software products that measure cost, quality, and utilization on a national basis. The products are certified by both the American College of Cardiology and the Society of Thoracic Surgery.

[2]Nonpayment of amounts owed pursuant to a contractual agreement does not, by itself, absolve parties from liability under the fraud and abuse laws.

[3]The Executive Summary for the Surgical Group is attached to this advisory opinion as Appendix A. This opinion is based on the specific cost savings recommendations and associated facts (e.g., specific floors or measurable quality indicators set for each recommendation) set forth in the Executive Summary. Similar cost savings recommendations involving different facts could produce a different result.

Executive Summary identified twenty-five specific recommendations that can be grouped roughly into the following four categories.

- *Disposable Cell Saver Components*. This category involved one recommendation that the Surgical Group refrain from opening disposable components of the cell saver unit until a patient experiences excessive bleeding, and, at the same time, that the Surgical Group implement specific alternative clinical practices. The Requestors have certified that the resulting delay in cell saver readiness did not exceed two to five minutes and did not adversely affect patient care.

- *"Use as Needed" Supplies*. For the second category, involving eight recommendations, the Surgical Group was to limit the use of certain surgical supplies to an as needed basis (hereafter, the "use as needed" recommendations). The Requestors have certified that the individual surgeons made patient-by-patient determinations as to whether these items were clinically indicated and that the surgical supplies remained readily available to the surgeons. The Requestors have further certified that any resulting limitations on the use of these products did not adversely affect patient care. Included in this category was a recommendation to limit use of Aprotinin– a medication given to many surgical patients pre-operatively to prevent hemorrhaging – to patients at higher risk of perioperative hemorrhage as indicated by objective clinical standards, as well as recommendations to eliminate the use of Vancomycin and Triple Antibiotic Ointment for particular procedures covered by the Arrangement.

- *Product Substitutions*. For the third category, involving eleven recommendations, the Surgical Group was to substitute, in whole or in part, less costly items for items then being used by the surgeons (hereafter, the "product substitution" recommendations). Some of the identified substitutions[4] would have no appreciable clinical significance (e.g., elbow pads, wrist splints, or skin staplers). For example, under one recommendation, surgeons were asked to utilize a reusable blanket instead of a disposable blanket. Other product substitutions involved pharmacy items and supplies that may have had appreciable clinical significance. With respect to these substitutions, the Requestors certified that the individual surgeon made a patient-by-patient determination whether the item or supply was clinically indicated and that all of the items and supplies remained readily available to the surgeons. The Requestors further certified that none of the identified product substitutions adversely impacted patient care.

[4]The Executive Summary identified with specificity the product substitution recommendations.

- *Product Standardization*. For the fourth category, involving five recommendations, the Surgical Group was to standardize the use of certain cardiac devices and supplies where medically appropriate. For this category, the Surgical Group was required to work with the Hospital to evaluate and clinically review vendors and products.[5] The Surgical Group agreed to use the selected products where medically appropriate, which might have required additional training or changes in clinical practice.

The Arrangement contained several safeguards intended to protect against inappropriate reductions in services. For many of the recommendations, the Arrangement used objective historical and clinical measures reasonably related to the practices and the patient population at the Hospital, and, in some cases, national data to establish "floors" below which no savings would accrue to the Surgical Group. For example, the cell saver was previously being set up for 100% of the cardiac procedures specified under the Arrangement, but was not actually used in all cases. The Arrangement established a 30% "floor" based upon best practice utilization. The Surgical Group has not been credited with any savings resulting from any reductions in cell saver use below this 30% floor. In other words, if cell saver use dropped below 30% of cases, no cost savings were allocated to the surgeons. Similarly for Aprotinin, the Arrangement established a 10% "floor" based upon national best practice data.[6] Under the Arrangement, savings from reduced use of Aprotinin have not been credited to the Surgical Group if the savings resulted from utilization of Aprotinin in fewer than 10% of cases or if the savings resulted from failure to use Aprotinin in a case that met the clinical indicators. All surgical cases – including cases in which Aprotinin was not administered – were reviewed by the Program Administrator to determine if the surgeons followed the objective clinical indicators.

For some recommendations, no "floors" were set because the identified substitutions had no appreciable clinical significance (e.g., use of blankets) or because eliminating usage of a pharmaceutical or supply comported with national best practice data and other quality indicators. However, to ensure that these recommendations did not adversely affect the quality of care at the Hospital, the Program Administrator tracked the Hospital's performance of the covered cardiac procedures against the quality indicators established by the Society of Thoracic Surgeons ("STS") throughout the base year and contract year (as defined below). According to the Requestors, the STS quality indicators against which all of the Arrangement's recommendations were evaluated reflect objective hospital baselines

[5]The Executive Summary identified with specificity the products at issue.

[6]According to the Requestors, the 10% floor represented a change in the national best practice baseline from an earlier 20% floor.

and incorporate specificity sufficient to correlate outcomes with operating room practices. The indicators are action-specific and not simply based on isolated patient outcome data unrelated to specific changes in operating room practices. No cost sharing amounts were allocated to the Surgical Group for procedures involving reductions in historical STS quality indicators.

Importantly, with respect to the product standardization recommendations for cardiac devices and supplies, the Requestors have certified that the individual surgeons made patient-by-patient determinations of the most appropriate device and the availability of the full range of cardiac devices was not compromised by the product standardization. The Requestors have further certified that individual physicians still had available the same selection of devices under the Arrangement as before and that the economies gained through the Arrangement resulted from inherent clinical and fiscal value and not from restricting the availability of devices.

According to the Program Administrator, to the extent implemented in accordance with the Executive Summary's specifications, the twenty-five recommendations presented substantial cost savings opportunities for the Hospital without any adverse impact on the quality of patient care.

Under the Arrangement, the Hospital intends to pay the Surgical Group 50% of the cost savings achieved by implementing the twenty-five recommendations in the Executive Summary for a period of one year. At the end of the applicable year (the "contract year"), cost savings were calculated separately for each of the twenty-five recommendations; this precluded shifting of cost savings and ensured that savings generated by utilization reduced below the set targets, as applicable, were not credited to the Surgical Group. The payment, when made, will constitute the entire compensation paid to the Surgical Group for services performed under the contract memorializing the Arrangement between the Surgical Group and the Hospital. For purposes of calculating the payment to the Surgical Group, the cost savings were calculated by subtracting the actual costs incurred during the contract year[7] for the items specified in the twenty-five recommendations when used by surgeons in the Surgical Group during the specified surgical procedures (the "contract year costs") from the historic costs for the same items when used during comparable surgical procedures in the base year[8] (the "base year costs"). The contract year costs were adjusted to account for any

[7]The contract year was the twelve-month term for which the Surgical Group would be compensated under the Arrangement.

[8]The "base year" was the twelve months preceding the contract year term. For purposes of this opinion, the Arrangement was limited to the one-year term of the contract; accordingly, this opinion is without force and effect with respect to any renewal or extension of the

inappropriate reductions in use of items beyond the targets set in the Executive Summary or in connection with reductions in the STS quality indicators. The payment to the Surgical Group was calculated to be 50% of the difference between the adjusted contract year costs and base year costs. Under the Arrangement, the Hospital is obligated to make an aggregate payment to the Surgical Group, which distributes its profits to each of its members on a *per capita* basis.

Calculation of the payment to the Surgical Group was also subject to the following limitations:

- If the Surgical Group's volume of procedures payable by a Federal health care program in the contract year exceeded the volume of like procedures payable by a Federal health care program performed in the base year, there was no sharing of cost savings for the additional procedures.

- To minimize the surgeons' financial incentive to steer more costly patients to other hospitals, the case severity, ages, and payors of the patient population treated under the Arrangement were monitored by a committee composed of representatives of the Requestors, using generally-accepted standards. If significant changes from historical measures indicated that a surgeon had altered his or her referral patterns in a manner beneficial to the Hospital as a result of the Arrangement, the surgeon at issue would have been terminated from participation in the Arrangement. No surgeons were terminated.

- The Executive Summary identified projected cost savings, and the aggregate payment to the Surgical Group, when made, will not exceed 50% of those amounts.

The Hospital and the Surgical Group documented the activities and the payment methodology under the Arrangement and agreed to make the documentation available to the Secretary of the United States Department of Health and Human Services, upon request. In addition, the Hospital and the Surgical Group disclosed the Arrangement to patients, including the fact that the Surgical Group's compensation was based on a percentage of the Hospital's cost savings. The disclosure was made to the patient before the patient was admitted to the Hospital for a procedure covered by the Arrangement; if pre-admission disclosure was impracticable (e.g., the patient is admitted for an unscheduled procedure or the need for the procedure is determined after admission), the disclosure was made before the patient consented to the surgery. The disclosures were made in writing, and patients had

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Arrangement. Notwithstanding, we note that any renewal or extension of the Arrangement would need to have incorporated updated base year costs.

an opportunity, if desired, to review details of the Arrangement, including the specific cost savings measures applicable to the patient's surgery.

II. LEGAL ANALYSIS

Arrangements like the Arrangement are designed to align incentives by offering physicians a portion of a hospital's cost savings in exchange for implementing cost saving strategies. Under the current reimbursement system, the burden of these costs falls on hospitals, not physicians. Payments to physicians based on cost savings may be intended to motivate them to reduce hospital costs associated with procedures performed by physicians at the hospitals.

Properly structured, arrangements that share cost savings can serve legitimate business and medical purposes. Specifically, properly structured arrangements may increase efficiency and reduce waste, thereby potentially increasing a hospital's profitability. However, such arrangements can potentially influence physician judgment to the detriment of patient care. Our concerns include, but are not limited to, the following: (i) stinting on patient care; (ii) "cherry picking" healthy patients and steering sicker (and more costly) patients to hospitals that do not offer such arrangements; (iii) payments in exchange for patient referrals; and (iv) unfair competition (a "race to the bottom") among hospitals offering cost savings programs to foster physician loyalty and to attract more referrals.

Hospital cost savings programs in general, and the Arrangement in particular, may implicate at least three Federal legal authorities: (i) the civil monetary penalty for reductions or limitations of direct patient care services provided to Federal health care program beneficiaries, sections 1128A(b)(1)-(2) of the Act; (ii) the anti-kickback statute, section 1128B(b) of the Act; and (iii) the physician self-referral law, section 1877 of the Act.[9] We address the first two of these authorities; section 1877 of the Act falls outside the scope of the OIG's advisory opinion authority. We express no opinion on the application of section 1877 of the Act to the Arrangement.

A. The Civil Monetary Penalty, Sections 1128A(b)(1)-(2) of the Act

Sections 1128A(b)(1)-(2) of the Act establish a civil monetary penalty ("CMP") against any hospital or critical access hospital that knowingly makes a payment directly or indirectly to

[9]In addition, nonprofit hospital arrangements raise issues of private inurement and private benefit under the Internal Revenue Service's income tax regulations in connection with section 501(c)(3) of the Internal Revenue Code. See Rev. Rul. 69-383, 1969-2 C.B. 113. We express no opinion on the application of the Internal Revenue Code to the Arrangement.

a physician (and any physician that receives such a payment) as an inducement to reduce or limit items or services to Medicare or Medicaid beneficiaries under the physician's direct care. Hospitals that make (and physicians that receive) such payments are liable for CMPs of up to $2,000 per patient covered by the payments. See id. There is no requirement that the prohibited payment be tied to a specific patient or to a reduction in medically necessary care. The CMP applies only to reductions or limitations of items or services provided to Medicare and Medicaid fee-for-service beneficiaries.[10]

The CMP prohibits payments by hospitals to physicians that may induce physicians to reduce or limit items or services furnished to their Medicare and Medicaid patients. A threshold inquiry is whether the Arrangement might have induced physicians to reduce or limit items or services. Given the specificity of the Arrangement, it is possible to review the opportunities for savings individually and evaluate their potential impact on patient care.

Having reviewed the twenty-five individual recommendations, we conclude that, except for a limited number of the identified product substitutions,[11] the recommendations implicated the CMP. Simply put, with respect to all but a handful of the recommendations, the Arrangement might have induced physicians to reduce or limit the then-current medical practice at the Hospital.[12] We recognize that the then-current medical practice may have involved care that exceeded the requirements of medical necessity. However, whether current medical practice reflects necessity or prudence is irrelevant for purposes of the CMP.

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[10]Physician incentive arrangements related to Medicare risk-based managed care contracts, similar Medicaid contracts, and Medicare Advantage plans (formerly Medicare + Choice) are subject to regulation by the Secretary pursuant to sections 1876(i)(8), 1903(m)(2)(A)(x), and 1852(j)(4) of the Act (respectively), in lieu of being subject to sections 1128A(b)(1)-(2). See OIG letter regarding hospital-physician incentive plans for Medicare and Medicaid beneficiaries enrolled in managed care plans (dated August 19, 1999), available at http://oig.hhs.gov/fraud/docs/alertsandbulletins/gsletter.htm. See also 42 C.F.R. § 417.479 (Medicare HMOs or competitive medical plans); 42 C.F.R. § 422.208 (Medicare Advantage plans); 42 C.F.R. § 438.6 (Medicaid risk plans).

[11]As described in Section I.B of this opinion, a few of the product substitution recommendations involved actions that should have had no appreciable clinical significance, such as substituting a reusable blanket for a disposable one. For these recommendations, we believe there would be no perceptible reduction or limitation in the provision of items or services to patients sufficient to trigger the CMP.

[12]This is true even though the Hospital has not yet paid the Surgical Group.

Notwithstanding, several features of the Arrangement, in combination, provided sufficient safeguards so that we would not seek sanctions against the Requestors under sections 1128A(b)(1)-(2) of the Act.

First, the specific cost-saving actions and resulting savings were clearly and separately identified. The transparency of the Arrangement allowed, and continues to allow, for public scrutiny and individual physician accountability for any adverse effects of the Arrangement, including any difference in treatment among patients based on nonclinical indicators. The transparency of the incentives for specific actions and specific procedures also facilitates accountability through the medical-legal professional liability system.

Second, the Requestors have proffered credible medical support for the position that implementation of the recommendations did not adversely affect patient care. The Arrangement was periodically reviewed by the Requestors to confirm that the Arrangement was not having an adverse impact on clinical care.[13]

Third, the amount to be paid under the Arrangement has been calculated based on all surgeries regardless of the patients' insurance coverage, subject to the cap on payment for Federal health care program procedures. Moreover, the surgical procedures to which the Arrangement applied were not disproportionately performed on Federal health care program beneficiaries. Additionally, the cost savings have been calculated on the Hospital's actual out-of-pocket acquisition costs, not an accounting convention.

Fourth, the Arrangement protected against inappropriate reductions in services by utilizing objective historical and clinical measures to establish baseline thresholds (or similar benchmarks) beyond which no savings accrued to the Surgical Group. The Requestors have certified that these baseline measures were reasonably related to the Hospital's or comparable hospitals' practices and patient populations. Moreover, the Requestors have certified that the STS quality indicators against which all of the Arrangement's recommendations were evaluated reflect objective hospital baselines and incorporate specificity sufficient to correlate outcomes with operating room practices; the indicators are action-specific and not simply based on isolated patient outcome data unrelated to specific

[13]We have had the Arrangement reviewed by an independent medical expert. The medical expert concluded that the cost savings measures, as described in the advisory opinion request and supplemental submissions, should not have adversely affected patient care. For purposes of this opinion, however, we rely solely on the Requestors' certifications and nothing in this advisory opinion should be construed as an endorsement or conclusion as to the medical propriety of the specific activities undertaken as part of the Arrangement.

changes in operating room practices. No cost sharing amounts were allocated to the Surgical Group where there were reductions in historical STS quality indicators.

Fifth, the product standardization portion of the Arrangement further protected against inappropriate reductions in services by ensuring that individual physicians still had available the same selection of devices and supplies under the Arrangement as before. The Arrangement was designed to produce savings through inherent clinical and fiscal value and not from restricting the availability of devices and supplies.

Sixth, the Hospital and the Surgical Group provided written disclosures of their involvement in the Arrangement to patients whose care might have been affected by the Arrangement and provided patients an opportunity to review the cost savings recommendations prior to admission to the Hospital (or, where pre-admission consent was impracticable, prior to consenting to surgery). While we do not believe that, standing alone, such disclosures offer sufficient protection from program or patient abuse, effective and meaningful disclosure offers some protection against possible abuses of patient trust.[14]

Seventh, the financial incentives under the Arrangement were reasonably limited in duration and amount.

Eighth, because Surgical Group distributes profits to its members on a *per capita* basis, any incentive for an individual surgeon to generate disproportionate cost savings is mitigated.

Our decision not to impose sanctions on the Requestors in connection with the Arrangement is an exercise of our discretion and is consistent with our Special Advisory Bulletin on "Gainsharing Arrangements and CMPs for Hospital Payments to Physicians to Reduce or Limit Services to Beneficiaries" (July 1999) (the "Special Advisory Bulletin"). We reiterate that the CMP applies to any payment by a hospital to a physician that is intended to induce the reduction or limitation of items or services to Medicare or Medicaid patients under the physician's direct clinical care. The Arrangement is markedly different from "gainsharing" plans that purport to pay physicians a percentage of generalized cost savings not tied to specific, identifiable cost-lowering activities. Importantly, the Arrangement set out the specific actions to be taken and tied the remuneration to the actual, verifiable cost savings attributable to those actions. This transparency allowed an assessment of the likely

[14]Ordinarily, we would expect patient disclosures to be coupled with patient satisfaction surveys that closely monitor patient perceptions of their care. However, in the context of the Arrangement, which focused on items used in operating rooms, we believe that patient satisfaction surveys would not have been effective.

effect of the Arrangement on quality of care and ensured that the identified actions caused the savings.

"Gainsharing" plans can present substantial risks for both patient and program abuse – risks that are not present in the Arrangement. Given the limited duration and scope of the Arrangement, the safeguards provided sufficient protections against patient and program abuse. Other arrangements, including those that are more expansive in scope or less specific than the Arrangement, are likely to require additional or different safeguards.

B. The Anti-Kickback Statute

The anti-kickback statute makes it a criminal offense knowingly and willfully to offer, pay, solicit, or receive any remuneration to induce or reward referrals of items or services reimbursable by a Federal health care program. See section 1128B(b) of the Act. Where remuneration is paid purposefully to induce or reward referrals of items or services payable by a Federal health care program, the anti-kickback statute is violated. By its terms, the statute ascribes criminal liability to parties on both sides of an impermissible "kickback" transaction. For purposes of the anti-kickback statute, "remuneration" includes the transfer of anything of value, directly or indirectly, overtly or covertly, in cash or in kind.

The statute has been interpreted to cover any arrangement where one purpose of the remuneration was to obtain money for the referral of services or to induce further referrals. United States v. Kats, 871 F.2d 105 (9th Cir. 1989); United States v. Greber, 760 F.2d 68 (3d Cir.), cert. denied, 474 U.S. 988 (1985). Violation of the statute constitutes a felony punishable by a maximum fine of $25,000, imprisonment up to five years, or both. Conviction will also lead to automatic exclusion from Federal health care programs, including Medicare and Medicaid. Where a party commits an act described in section 1128B(b) of the Act, the OIG may initiate administrative proceedings to impose civil monetary penalties on such party under section 1128A(a)(7) of the Act. The OIG may also initiate administrative proceedings to exclude such party from the Federal health care programs under section 1128(b)(7) of the Act.

The Department of Health and Human Services has promulgated safe harbor regulations that define practices that are not subject to the anti-kickback statute because such practices would be unlikely to result in fraud or abuse. See 42 C.F.R. § 1001.952. The safe harbors set forth specific conditions that, if met, assure entities involved of not being prosecuted or sanctioned for the arrangement qualifying for the safe harbor. However, safe harbor protection is afforded only to those arrangements that precisely meet all of the conditions set forth in the safe harbor.

The safe harbor for personal services and management contracts, 42 C.F.R. §1001.952(d), is potentially applicable to the Arrangement. In relevant part for purposes of this advisory opinion, the personal services safe harbor requires that the aggregate compensation paid for the services be set in advance and consistent with fair market value in arm's-length transactions. The Arrangement can not fit in the safe harbor because the payment owed to the Surgical Group was calculated on a percentage basis, and thus the aggregate compensation was not set in advance. However, the absence of safe harbor protection is not fatal. Instead, the Arrangement must be subject to case-by-case evaluation.

As with any compensation arrangement between a hospital and a physician who admits or refers patients to the hospital, we are concerned that the Arrangement could have been used to disguise remuneration from the Hospital to reward or induce referrals by the Surgical Group or its surgeons. Specifically, the Arrangement could have encouraged the surgeons to admit Federal health care program patients to the Hospital, since the surgeons would receive not only their Medicare Part B professional fee, but also, indirectly, a share of the Hospital's payment, depending on cost savings. In other words, the more procedures a surgeon performed at the Hospital, the more money he or she was likely to receive under the Arrangement.

While we believe the Arrangement might have resulted in illegal remuneration if the requisite intent to induce referrals were present, we would not impose sanctions in the particular circumstances presented here and as qualified below.

First, the circumstances and safeguards of the Arrangement reduce the likelihood that the Arrangement was used to attract referring physicians or to increase referrals from existing physicians. Specifically, participation in the Arrangement was limited to surgeons already on the medical staff, thus limiting the likelihood that the Arrangement would attract other surgeons. In addition, the potential savings derived from procedures for Federal health care program beneficiaries were capped based on the prior year's admissions of Federal health care program beneficiaries. Finally, the contract year for which payments were calculated was limited to one year, reducing any incentive for physicians to switch facilities to earn cost savings payments, and patient admissions were monitored for changes in severity, age, or payor to ensure that the Arrangement did not result in inappropriate changes in referral patterns. Thus, while the incentive to refer was not necessarily eliminated, it was substantially reduced.

Second, the structure of the Arrangement eliminated the risk that the Arrangement might have been used to reward cardiologists or other physicians who refer patients to the Surgical Group or its surgeons. The Surgical Group is the sole participant in the Arrangement and is composed entirely of cardiac surgeons; no cardiologists or other physicians are members of the Surgical Group or share in its profit distributions. Within the Surgical Group, profits are

distributed to its members on a *per capita* basis, mitigating any incentive for an individual surgeon to generate disproportionate cost savings.

Third, the Arrangement set out with specificity the particular actions that generated the cost savings on which the payments are based. While many of the recommendations in the Executive Summary are simple common sense, they did represent a change in operating room practice, for which the surgeon was responsible and has liability exposure. While most of the recommendations appear to present minimal risk, the preparation of the cell saver, limiting the use of certain surgical supplies, product substitution of pharmacy items and supplies, and product standardization each carried some increased liability risk for the physicians. It is not unreasonable for the surgeon to receive compensation for the increased risk from the change in practice. Moreover, the payments to be made under the Arrangement represent a portion of one year's worth of cost savings and are limited in amount (i.e., the aggregate cap), duration (i.e., the limited contract term), and scope (i.e., the total savings that could be achieved from the implementation of any one recommendation were limited by appropriate utilization levels). The payments under the Arrangement do not appear unreasonable, given, among other things, the nature of the actions required of the physicians to have implemented the twenty-five recommended actions, the specificity of the payment formula, and the cap on total remuneration to the Surgical Group.[15] We caution that payments of 50% of cost savings in other arrangements, including multi-year arrangements or arrangements with generalized cost savings formulae, could well lead to a different result.

In light of these circumstances and safeguards, the Arrangement poses a low risk of fraud or abuse under the anti-kickback statute.

III. CONCLUSION

Notwithstanding the foregoing, we reiterate our concerns regarding many arrangements between hospitals and physicians to share cost savings. Improperly designed or implemented arrangements risk adversely affecting patient care and could be vehicles to disguise payments for referrals. For example, an arrangement that cannot be adequately and accurately measured for quality of care would pose a high risk of fraud or abuse, as would one that rewards physicians based on overall cost savings without accountability for specific

[15]We are precluded by statute from opining on whether fair market value shall be or was paid for goods, services, or property. See 42 U.S.C. § 1320a-7d(b)(3)(A). While the Requestors have certified that the payments owed under the Arrangement are consistent with fair market value, we do not rely on that certification in this opinion, nor have we have made an independent fair market value assessment.

cost reduction measures. Moreover, arrangements structured so as to pose a heightened potential for patient steering and unfair competition would be considered suspect. In short, this opinion is predicated on the specific arrangement posed by the Requestors and is limited to that specific arrangement. Other apparently similar arrangements could raise different concerns and lead to a different result.

Based on the facts certified in your request for an advisory opinion and supplemental submissions, we conclude: (i) the Arrangement could constitute an improper payment to induce reduction or limitation of services pursuant to sections 1128A(b)(1)-(2) of the Act, but that the OIG would not impose sanctions under sections 1128A(b)(1)-(2) on the Requestors in connection with the Arrangement; and (ii) the Arrangement could potentially generate prohibited remuneration under the anti-kickback statute, if the requisite intent to induce or reward referrals of Federal health care program business were present, but that the OIG would not impose administrative sanctions on the Requestors under sections 1128(b)(7) or 1128A(a)(7) of the Act (as those sections relate to the commission of acts described in section 1128B(b) of the Act) in connection with the Arrangement.

IV. LIMITATIONS

The limitations applicable to this opinion include the following:

- This advisory opinion is issued only to [names redacted], the requestors of this opinion. This advisory opinion has no application to, and cannot be relied upon by, any other individual or entity.

- This advisory opinion may not be introduced into evidence in any matter involving an entity or individual that is not a requestor to this opinion.

- This advisory opinion is applicable only to the statutory provisions specifically noted above. No opinion is expressed or implied herein with respect to the application of any other Federal, state, or local statute, rule, regulation, ordinance, or other law that may be applicable to the Arrangement, including, without limitation, the physician self-referral law, section 1877 of the Act.

- This advisory opinion will not bind or obligate any agency other than the U.S. Department of Health and Human Services.

- This advisory opinion is limited in scope to the specific arrangement described in this letter and has no applicability to other arrangements, even those that appear similar in nature or scope.

- No opinion is expressed herein regarding the liability of any party under the False Claims Act or other legal authorities for any improper billing, claims submission, cost reporting, or related conduct.

This opinion is also subject to any additional limitations set forth at 42 C.F.R. Part 1008.

The OIG will not proceed against the Requestors with respect to any action that is part of the Arrangement taken in good faith reliance upon this advisory opinion, as long as all of the material facts have been fully, completely, and accurately presented, and the Arrangement in practice comports with the information provided. The OIG reserves the right to reconsider the questions and issues raised in this advisory opinion and, where the public interest requires, to rescind, modify, or terminate this opinion. In the event that this advisory opinion is modified or terminated, the OIG will not proceed against the Requestors with respect to any action taken in good faith reliance upon this advisory opinion, where all of the relevant facts were fully, completely, and accurately presented, and where such action was promptly discontinued upon notification of the modification or termination of this advisory opinion. An advisory opinion may be rescinded only if the relevant and material facts have not been fully, completely, and accurately disclosed to the OIG.

Sincerely,

/s/

Lewis Morris
Chief Counsel to the Inspector General

[Appendix A redacted]

[*We redact certain identifying information and certain potentially privileged, confidential, or proprietary information associated with the individual or entity, unless otherwise approved by the requestor.*]

Issued: July 31, 2008

Posted: August 7, 2008

To: ATTACHED DISTRIBUTION LIST

Re: OIG Advisory Opinion No. 08-09

Ladies & Gentlemen:

We are writing in response to your request for an advisory opinion concerning an arrangement under which a medical center has agreed to share with groups of orthopedic surgeons and a group of neurosurgeons a percentage of the medical center's cost savings arising from the surgeons' implementation of a number of cost reduction measures in certain surgical procedures (the "Arrangement"). The cost savings are measured based on the surgeons' reduction of waste and use of specific medical devices and supplies during designated spine fusion surgery procedures. You have inquired whether the Arrangement constitutes grounds for sanctions arising under: (i) the civil monetary penalty for a hospital's payment to a physician to induce reductions or limitations of services to Medicare or Medicaid beneficiaries under the physician's direct care, sections 1128A(b)(1)-(2) of the Social Security Act (the "Act"); or (ii) the exclusion authority at section 1128(b)(7) of the Act or the civil monetary penalty provision at section 1128A(a)(7) of the Act, as those sections relate to the commission of acts described in section 1128B(b) of the Act, the anti-kickback statute.

You have certified that all of the information provided in your request, including all supplementary letters, is true and correct and constitutes a complete description of the relevant facts and agreements among the parties.

In issuing this opinion, we have relied solely on the facts and information presented to us. We have not undertaken an independent investigation of such information. This opinion is limited to the facts presented. If material facts have not been disclosed or have been misrepresented, this opinion is without force and effect.

Based on the information provided and the totality of the facts described and certified in your request for an advisory opinion and supplemental submissions, we conclude that: (i) the Arrangement constitutes an improper payment to induce reduction or limitation of services pursuant to sections 1128A(b)(1)-(2) of the Act, but that the Office of Inspector General ("OIG") will not impose sanctions on the requestors of this advisory opinion, [names redacted] (collectively, the "Requestors"), in connection with the Arrangement; and (ii) the Arrangement potentially generates prohibited remuneration under the anti-kickback statute, if the requisite intent to induce or reward referrals of Federal health care program business were present, but that the OIG will not impose administrative sanctions on the Requestors under sections 1128(b)(7) or 1128A(a)(7) of the Act (as those sections relate to the commission of acts described in section 1128B(b) of the Act) in connection with the Arrangement.

This opinion may not be relied on by any persons other than the Requestors and is further qualified as set out in Part IV below and in 42 C.F.R. Part 1008.

I. FACTUAL BACKGROUND

A. Parties

The Medical Center. [Name redacted] Medical Center (the "Medical Center") is an academic medical center in [city and state names redacted] that offers a broad range of inpatient and outpatient hospital services, including spine fusion surgery services. The Medical Center is a participating provider in the Medicare and Medicaid programs.

The Orthopedic Surgery Groups. [Names redacted] (the "Orthopedic Surgery Groups") are group medical practices that employ only orthopedic surgeons. The members of the Orthopedic Surgery Groups participating in the Arrangement are licensed in the State of [state name redacted] and have active medical staff privileges at the Medical Center.[1] They refer patients to the Medical Center for inpatient and outpatient hospital services. Both groups entered into a separate contract with the Medical Center that set forth the projected savings opportunities applicable to the group.

The Neurosurgery Group. [Name redacted] (the "Neurosurgery Group") employs only neurosurgeons. The members of the Neurosurgery Group participating in the arrangement are licensed in the State of [state name redacted] and have active medical staff privileges at the Medical Center.[2] The Neurosurgery Group refers patients to the

[1]The Orthopedic Surgery Groups include members who also practice at other hospitals in the region; however, the Medical Center is the primary practice location for most members of the Orthopedic Surgery Groups.

Medical Center for inpatient and outpatient hospital services. The Neurosurgery Group entered into a separate contract with the Medical Center that set forth the projected savings opportunities applicable to the group.

The Program Administrator. The Medical Center engaged [name redacted] (the "Program Administrator") to administer the Arrangement. The Program Administrator collected data and analyzed and manages the Arrangement.[3] The Medical Center paid the Program Administrator a monthly fixed fee certified by the Requestors to be fair market value in an arm's-length transaction for services provided by the Program Administrator under the Arrangement. The fee was not tied in any way to cost savings or to the compensation of the Orthopedic Surgery Groups and the Neurosurgery Group under the Arrangement.

B. The Arrangement

Under the Arrangement, the Medical Center agreed to pay the Orthopedic Surgery Groups and the Neurosurgery Group a share of the first year cost savings directly attributable to specific changes made in the Orthopedic Surgery Groups' and the Neurosurgery Group's operating room practices. The Requestors implemented the Arrangement – and the Orthopedic Surgery Groups and the Neurosurgery Group began performance of the specific changes in operating room practices – prior to requesting this advisory opinion. However, the Medical Center has not paid amounts owed to the Orthopedic Surgery Groups and the Neurosurgery Group under the Arrangement pending the outcome of this opinion.[4] Thus, we are treating the Arrangement as an existing arrangement for purposes of this advisory opinion. The Requestors have certified that the Medical Center will make payments owed under the Arrangement upon receipt of a favorable advisory opinion.

To develop the Arrangement, the Program Administrator conducted a study of historic practices in spine fusion surgery by the Orthopedic Surgery Groups and the Neurosurgery Group at the Medical Center and identified thirty-six specific cost-savings opportunities. The Program Administrator summarized the results of the study of the historic practices of the Orthopedic Surgery Groups and the Neurosurgery Group and the specific cost-

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[2]The Neurosurgery Group includes members who also practice at other hospitals in the region; however, the Medical Center is the primary practice location for most members of the Neurosurgery Group.

[3]The Program Administrator has developed software products that measure cost, quality, and utilization on a national basis.

[4]Nonpayment of amounts owed pursuant to a contractual agreement does not, by itself, absolve parties from liability under the fraud and abuse laws.

savings opportunities in a document entitled, "Executive Summary [name redacted] Valueshare for Spine Surgery" (the "Executive Summary").

The Medical Center, the Orthopedic Surgery Groups and the Neurosurgery Group reviewed the Executive Summary for medical appropriateness and each adopted its recommendations and conclusions.[5]

In general, the Executive Summary recommended that the Orthopedic Surgery Groups and the Neurosurgery Group change their operating room practices to standardize the use of spine fusion devices and supplies. The Executive Summary identified thirty-six specific recommendations that can be roughly grouped into the following two categories.

- *"Use as Needed" Biological*. The first category, containing a single recommendation, involved limiting the use of Bone Morphogenetic Protein ("BMP") to an as needed basis. The Requestors have certified that the individual surgeon made patient-by-patient determinations as to whether BMP was clinically indicated and that the biological remained readily available to the surgeons. The Requestors further certified that any resulting limitation on the use of BMP did not adversely affect patient care.

- *Product Standardization.* For the second category, involving thirty-five recommendations, the Orthopedic Surgery Groups and the Neurosurgery Group were to standardize the use of certain spine fusion devices and supplies where medically appropriate. For this category, the Orthopedic Surgery Groups and the Neurosurgery Group were required to work in conjunction with the Medical Center to evaluate and clinically review vendors and products.[6] The Orthopedic Surgery Groups and the Neurosurgery Group agreed to use the selected products where medically appropriate, which may have required additional training or changes in clinical practice.

The Arrangement contained several safeguards intended to protect against inappropriate reductions in services. With respect to the use as needed recommendation, the Arrangement utilized objective historical and clinical measures reasonably related to the

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[5]The Executive Summary, dated December 31, 2006, is attached to this advisory opinion as Appendix A. The approaches of the orthopedic surgeons and the neurosurgeons to spine fusion surgery overlap, often making use of same methods, devices, and supplies. No distinctions are made in the Executive Summary between the two types of surgeons in terms of past practices or gainsharing recommendations.

[6]The Executive Summary identified with specificity the vendors and products at issue.

practices and the patient population at the Medical Center to establish a "floor" beyond which no savings would accrue to the Orthopedic Surgery Groups or the Neurosurgery Group. The Arrangement used specific, objective, generally-accepted clinical indicators reasonably related to the practices of the Medical Center and its patient population to determine medical appropriateness.

Before the implementation of the Arrangement, BMP had been used in approximately 15% of patients undergoing spine fusion procedures by the Orthopedic Surgery Groups and the Neurosurgery Group. The Program Administrator determined through analysis of national data that it was reasonable to reduce the use of BMP on these cases to 11% of patients and that this reduction would not adversely impact patient care. Under the Arrangement, savings from reduced use of BMP were not credited to the Orthopedic Surgery Groups and the Neurosurgery Group if the savings resulted from utilization of BMP in less than 11% of cases or if the savings resulted from failure to use BMP in a case that met the clinical indicators. All surgical cases – including cases in which BMP was not administered – were reviewed by the Program Administrator to determine if the surgeons followed the objective clinical indicators for determining whether BMP was used appropriately.

Importantly, with respect to the product standardization recommendations, the Requestors certified that the individual surgeons made a patient-by-patient determination of the most appropriate spine fusion devices and supplies and the availability of the full range of devices and supplies was not compromised by the product standardization. The Requestors further certified that individual physicians still had available the same selection of devices and supplies after implementation of the Arrangement as before and that the economies gained through the Arrangement resulted from inherent clinical and fiscal value and not from restricting the availability of devices and supplies.

According to the Program Administrator, if implemented in accordance with the Executive Summary's specifications, the thirty-six recommendations presented substantial cost savings opportunities for the Medical Center without adversely impacting the quality of patient care.

Under the Arrangement, the Medical Center intends to pay each of the Orthopedic Surgery Groups and the Neurosurgery Group individually for 50% of the cost savings achieved by the respective group when implementing the thirty-six recommendations in the Executive Summary for a period of one year. At the end of the applicable year (the "contract year"), cost savings were calculated separately for each group and for each of the thirty-six recommendations; this precluded shifting of cost savings and ensured that savings generated by utilization beyond set targets, as applicable were not credited to the Orthopedic Surgery Groups or the Neurosurgery Group.

The payments, when made, to the Orthopedic Surgery Groups and Neurosurgery Groups, respectively, will constitute the entire compensation paid to the Orthopedic Surgery Groups and the Neurosurgery Group for services performed under the contracts memorializing the Arrangement between the respective groups and the Medical Center. For purposes of calculating the payments to the Orthopedic Surgery Groups and the Neurosurgery Group, the cost savings were calculated by subtracting the actual costs incurred during the contract year[7] for the items specified in the thirty-six recommendations when used by surgeons in each respective group, as applicable, during the specified surgical procedures (the "contract year costs") from the historic costs for the same items when used by the particular group during comparable surgical procedures in the base year (the "base year costs"[8]). The contract year costs were adjusted to account for any inappropriate reductions in use of items beyond the targets set in the Executive Summary. The payments to the Orthopedic Surgery Groups and the Neurosurgery Group, when made, will be 50% of the difference between each respective group's adjusted current year costs and the base year costs less 50% of the costs incurred by the Medical Center to administer the Arrangement.

Under the Arrangement, the Medical Center is obligated to make aggregate payments to the practices which comprise the Orthopedic Surgery Groups and the Neurosurgery Group, each of which distributes its respective profits among its members on a per capita basis.

Calculation of payments to the Orthopedic Surgery Groups and the Neurosurgery Group was subject to the following limitations:

- If the volumes of procedures payable by a Federal health care program performed by each of the three physician groups in the gainsharing year exceeded that individual group's volume of like procedures payable by a Federal health care program performed in the base year, there was no sharing of cost savings for the additional procedures.

- To minimize the surgeons' financial incentive to steer more costly patients to other hospitals, the case severity, ages, and payors of the patient population treated under the Arrangement were monitored by a committee composed of

[7]The contract year was the twelve-month term for which the Orthopedic Surgery Groups and the Neurosurgery Group were compensated under the Arrangement.

[8]The "base year" was the twelve months preceding the effective date of the contracts. For purposes of this opinion, the Arrangement is limited to the one-year term of the contracts; accordingly, this opinion is without force and effect with respect to any future renewal or extension of the Arrangement. Notwithstanding, we note that any renewal or extension of the Arrangement should incorporate updated base year costs.

representatives of the Requestors, using generally-accepted standards. If significant changes from historical measures indicated that a surgeon had altered his or her referral patterns in a manner beneficial to the Medical Center as a result of the Arrangement, the surgeon at issue would have been terminated from participation in the Arrangement. No surgeons were terminated.

- The Executive Summary identified projected cost savings, and the aggregate of payments to the Orthopedic Surgery Groups and the Neurosurgery Group, when made, will not exceed 50% of the group's share of projected cost savings; each group, furthermore, will be compensated solely for its own savings under the Arrangement.

The Medical Center, the Orthopedic Surgery Groups, and the Neurosurgery Group documented the activities and the payment methodology under the Arrangement and agreed to make the documentation available to the Secretary of the United States Department of Health and Human Services, upon request. In addition, the Medical Center, the Orthopedic Surgery Groups, and the Neurosurgery Group disclosed the Arrangement to the patients, including the fact that compensation of the Orthopedic Surgery Groups and the Neurosurgery Group was based on a percentage of the Medical Center's cost savings. The disclosure was made to the patient before the patient was admitted to the Medical Center for a procedure covered by the Arrangement; if pre-admission disclosure was impracticable (e.g., the patient was admitted for an unscheduled procedure or the need for the procedure is determined after admission), the disclosure was made before the patient consented to the surgery. The disclosures were made in writing, and patients had an opportunity, if desired, to review details of the Arrangement, including the specific cost savings measures applicable to the patient's surgery.

II. LEGAL ANALYSIS

Arrangements like the Arrangement are designed to align incentives by offering physicians a portion of a hospital's cost savings in exchange for implementing cost saving strategies. Under the current reimbursement system, the burden of these costs falls on hospitals, not physicians. Payments to physicians based on cost savings may be intended to motivate them to reduce hospital costs associated with procedures performed by physicians at the hospitals.

Properly structured, arrangements that share cost savings can serve legitimate business and medical purposes. Specifically, properly structured arrangements may increase efficiency and reduce waste, thereby potentially increasing a hospital's profitability. However, such arrangements can potentially influence physician judgment to the detriment of patient care. Our concerns include, but are not limited to, the following: (i) stinting on patient care; (ii) "cherry picking" healthy patients and steering sicker (and

more costly) patients to hospitals that do not offer such arrangements; (iii) payments in exchange for patient referrals; and (iv) unfair competition (a "race to the bottom") among hospitals offering cost savings programs to foster physician loyalty and to attract more referrals.

Hospital cost savings programs in general, and the Arrangement in particular, may implicate at least three Federal legal authorities: (i) the civil monetary penalty for reductions or limitations of direct patient care services provided to Federal health care program beneficiaries, sections 1128A(b)(1)-(2) of the Act; (ii) the anti-kickback statute, section 1128B(b) of the Act; and (iii) the physician self-referral law, section 1877 of the Act.[9] We address the first two of these authorities; section 1877 of the Act falls outside the scope of the OIG's advisory opinion authority. We express no opinion on the application of section 1877 of the Act to the Arrangement.

A. The Civil Monetary Penalty, Sections 1128A(b)(1)-(2) of the Act

Sections 1128A(b)(1)-(2) of the Act establish a civil monetary penalty ("CMP") against any hospital or critical access hospital that knowingly makes a payment directly or indirectly to a physician (and any physician that receives such a payment) as an inducement to reduce or limit items or services to Medicare or Medicaid beneficiaries under the physician's direct care. Hospitals that make (and physicians that receive) such payments are liable for CMPs of up to $2,000 per patient covered by the payments. See id. There is no requirement that the prohibited payment be tied to a specific patient or to a reduction in medically necessary care. The CMP applies only to reductions or limitations of items or services provided to Medicare and Medicaid fee-for-service beneficiaries.[10]

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[9]In addition, nonprofit hospital arrangements raise issues of private inurement and private benefit under the Internal Revenue Service's income tax regulations in connection with section 501(c)(3) of the Internal Revenue Code. See Rev. Rul. 69-383, 1969-2 C.B. 113. We express no opinion on the application of the Internal Revenue Code to the Arrangement.

[10]Physician incentive arrangements related to Medicare risk-based managed care contracts, similar Medicaid contracts, and Medicare Advantage plans (formerly Medicare + Choice) are subject to regulation by the Secretary pursuant to sections 1876(i)(8), 1903(m)(2)(A)(x), and 1852(j)(4) of the Act (respectively), in lieu of being subject to sections 1128A(b)(1)-(2). See OIG letter regarding hospital-physician incentive plans for Medicare and Medicaid beneficiaries enrolled in managed care plans (dated August 19, 1999), available at http://oig.hhs.gov/fraud/docs/alertsandbulletins/gsletter.htm. See also 42 C.F.R. § 417.479 (Medicare HMOs or competitive medical plans); 42 C.F.R. § 422.208 (Medicare Advantage plans); 42 C.F.R. § 438.6 (Medicaid risk plans).

The CMP prohibits payments by hospitals to physicians that may induce physicians to reduce or limit items or services furnished to their Medicare and Medicaid patients. A threshold inquiry is whether the Arrangement will induce physicians to reduce or limit items or services. Given the specificity of the Arrangement, it is possible to review the proposed opportunities for savings individually and evaluate their potential impact on patient care.

Having reviewed the thirty-six individual recommendations, we conclude that the recommendations implicated the CMP. Simply put, the Arrangement might have induced physicians to reduce or limit the then-current medical practice at the Medical Center.[11] We recognize that the then-current medical practice may have involved care that exceeded the requirements of medical necessity. However, whether current medical practice reflects necessity or prudence is irrelevant for purposes of the CMP.

In sum, we find that the CMP applied to the recommendations for the standardization of devices and supplies, and limiting the use of BMP. Notwithstanding, several features of the Arrangement, in combination, provide sufficient safeguards so that we would not seek sanctions against the Requestors under sections 1128A(b)(1)-(2) of the Act.

First, the specific cost-saving actions and resulting savings were clearly and separately identified. The transparency of the Arrangement allows for public scrutiny and individual physician accountability for any adverse effects of the Arrangement, including any difference in treatment among patients based on nonclinical indicators. The transparency of the incentives for specific actions and specific procedures also facilitates accountability through the medical-legal professional liability system.

Second, the Requestors proffered credible medical support for the position that implementation of the recommendations did not adversely affect patient care. The Arrangement was periodically reviewed by the Requestors to confirm that the Arrangement was not having an adverse impact on clinical care.[12]

Third, the amount to be paid under the Arrangement was calculated based on all surgeries regardless of the patients' insurance coverage, subject to the cap on payment for Federal

[11] This is true even though the Medical Center has not yet paid the Orthopedic Surgery Groups and the Neurosurgery Group.

[12] We have had the Arrangement reviewed by an independent medical expert who has concluded that the cost savings measures, as described in the advisory opinion request and supplemental submissions, should not have adversely affected patient care. For purposes of this opinion, however, we rely solely on the Requestors' certifications and nothing in this advisory opinion should be construed as an endorsement or conclusion as to the medical propriety of the specific activities undertaken as part of the Arrangement.

health care program procedures. Moreover, the surgical procedures to which the Arrangement applies were not disproportionately performed on Federal health care program beneficiaries. Additionally, the cost savings are calculated from the Medical Center's actual out-of-pocket acquisition costs, not an accounting convention.

Fourth, the Arrangement protected against inappropriate reductions in services by utilizing objective historical and clinical measures to establish baseline thresholds beyond which no savings accrued to the Orthopedic Surgery Groups or the Neurosurgery Group. The Requestors have certified that these baseline measures were reasonably related to the Medical Center's or comparable hospitals' practices and patient populations. These safeguards were action-specific and not simply based on isolated patient outcome data unrelated to the specific changes in operating room practices.

Fifth, the product standardization portion of the Arrangement further protected against inappropriate reductions in services by ensuring that individual physicians still had available the same selection of devices and supplies after implementation of the Arrangement as before. The Arrangement was designed to produce savings through inherent clinical and fiscal value and not from restricting the availability of devices and supplies.

Sixth, the Medical Center, the Orthopedic Surgery Groups, and the Neurosurgery Group provided written disclosures of their involvement in the Arrangement to patients whose care might have been affected by the Arrangement and provided patients an opportunity to review the cost savings recommendations prior to admission to the Medical Center (or, where pre-admission consent was impracticable, prior to consenting to surgery). While we do not believe that, standing alone, such disclosures offer sufficient protection from program or patient abuse, effective and meaningful disclosure offers some protection against possible abuses of patient trust.[13]

Seventh, the financial incentives under the Arrangement were reasonably limited in duration and amount.

Eighth, because the Orthopedic Surgery Groups and the Neurosurgery Group distribute profits to their respective members on a per capita basis, any incentive for an individual surgeon to generate disproportionate cost savings was mitigated.

Our decision not to impose sanctions on the Requestors in connection with the Arrangement is an exercise of our discretion and is consistent with our Special Advisory

[13]Ordinarily, we would expect patient disclosures to be coupled with patient satisfaction surveys that closely monitor patient perceptions of their care. However, in the context of the Arrangement, which focused on items used in operating rooms, we believe that patient satisfaction surveys would not have been effective.

Bulletin on "Gainsharing Arrangements and CMPs for Medical Center Payments to Physicians to Reduce or Limit Services to Beneficiaries" (July 1999) (the "Special Advisory Bulletin"). We reiterate that the CMP applies to any payment by a hospital to a physician that is intended to induce the reduction or limitation of items or services to Medicare or Medicaid patients under the physician's direct clinical care. The Arrangement is markedly different from many "gainsharing" plans that purport to pay physicians a percentage of generalized cost savings not tied to specific, identifiable cost-lowering activities. Importantly, the Arrangement set out the specific actions to be taken and tied the remuneration to the actual, verifiable cost savings attributable to those actions. This transparency allowed an assessment of the likely effect of the Arrangement on quality of care and ensured that the identified actions caused the savings.

Many "gainsharing" plans present substantial risks for both patient and program abuse – risks that were not present in the Arrangement. Given the limited duration and scope of the Arrangement, the safeguards provided sufficient protections against patient and program abuse. Other arrangements, including those that are more expansive in scope or less specific than the Arrangement, are likely to require additional or different safeguards.

B. The Anti-Kickback Statute

The anti-kickback statute makes it a criminal offense knowingly and willfully to offer, pay, solicit, or receive any remuneration to induce or reward referrals of items or services reimbursable by a Federal health care program. See section 1128B(b) of the Act. Where remuneration is paid purposefully to induce or reward referrals of items or services payable by a Federal health care program, the anti-kickback statute is violated. By its terms, the statute ascribes criminal liability to parties on both sides of an impermissible "kickback" transaction. For purposes of the anti-kickback statute, "remuneration" includes the transfer of anything of value, directly or indirectly, overtly or covertly, in cash or in kind.

The statute has been interpreted to cover any arrangement where one purpose of the remuneration was to obtain money for the referral of services or to induce further referrals. United States v. Kats, 871 F.2d 105 (9th Cir. 1989); United States v. Greber, 760 F.2d 68 (3d Cir.), cert. denied, 474 U.S. 988 (1985). Violation of the statute constitutes a felony punishable by a maximum fine of $25,000, imprisonment up to five years, or both. Conviction will also lead to automatic exclusion from Federal health care programs, including Medicare and Medicaid. Where a party commits an act described in section 1128B(b) of the Act, the OIG may initiate administrative proceedings to impose civil monetary penalties on such party under section 1128A(a)(7) of the Act. The OIG may also initiate administrative proceedings to exclude such party from the Federal health care programs under section 1128(b)(7) of the Act.

The Department of Health and Human Services has promulgated safe harbor regulations that define practices that are not subject to the anti-kickback statute because such practices would be unlikely to result in fraud or abuse. See 42 C.F.R. § 1001.952. The safe harbors set forth specific conditions that, if met, assure entities involved of not being prosecuted or sanctioned for the arrangement qualifying for the safe harbor. However, safe harbor protection is afforded only to those arrangements that precisely meet all of the conditions set forth in the safe harbor.

The safe harbor for personal services and management contracts, 42 C.F.R. §1001.952(d), is potentially applicable to the Arrangement. In relevant part for purposes of this advisory opinion, the personal services safe harbor requires that the aggregate compensation paid for the services be set in advance and consistent with fair market value in arm's-length transactions. The Arrangement can not fit in the safe harbor because the payment owed to the Orthopedic Surgery Groups and the Neurosurgery Group was calculated on a percentage basis, and thus the compensation could not be set in advance. However, the absence of safe harbor protection is not fatal. Instead, the Arrangement must be subject to case-by-case evaluation.

We are concerned that the Arrangement, like any compensation arrangement between a hospital and a physician who admits or refers patients to such hospital, could be used to disguise remuneration from the Medical Center to reward or induce referrals by the Orthopedic Surgery Groups or the Neurosurgery Group. Specifically, the Arrangement could have encouraged the surgeons to admit Federal health care program patients to the Medical Center, since the surgeons would receive not only their Medicare Part B professional fee, but also, indirectly, a share of the Medical Center's payment, depending on cost savings. In other words, the more procedures a surgeon performed at the Medical Center, the more money he or she is likely to have received under the Arrangement.

While we believe the Arrangement might have resulted in illegal remuneration if the requisite intent to induce referrals were present, we will not impose sanctions in the particular circumstances presented here and as qualified below.

First, the circumstances and safeguards of the Arrangement reduced the likelihood that the Arrangement was used to attract referring physicians or to increase referrals from existing physicians. Specifically, participation in the Arrangement was limited to surgeons already on the medical staff, thus limiting the likelihood that the Arrangement would attract other surgeons. In addition, the potential savings derived from procedures for Federal health care program beneficiaries were capped based on the participating physicians' prior year's admissions of Federal health care program beneficiaries. Finally, the contracts' terms were limited to one year, reducing any incentive to switch facilities, and admissions were monitored for changes in severity, age, or payor. Thus, while the incentive to refer was not necessarily eliminated, it was substantially reduced.

Second, the structure of the Arrangement eliminated the risk that the Arrangement might be used to reward surgeons or other physicians who refer patients to the Orthopedic Surgery Groups, the Neurosurgery Group, or their surgeons. The Orthopedic Surgery Groups and the Neurosurgery Group, the only participants in the Arrangement, were composed entirely of surgeons who perform spine fusion surgery; no other types of physicians were members of the Orthopedic Surgery Groups or the Neurosurgery Group, or shared in their profit distributions. Within each of the three practices, profits were distributed to members on a per capita basis, mitigating any incentive for an individual surgeon to generate disproportionate cost savings.

Third, the Arrangement set out with specificity the particular actions that generated the cost savings on which the payments will be based. The recommendations represented a change in operating room practice, for which the surgeon was responsible and had liability exposure. Product standardization and limiting the use of BMP each carried some increased liability risk for the physicians. It is not unreasonable for the surgeon to receive compensation for the increased risk from the change in practice. Moreover, the payments to be made under the Arrangement represent a portion of one year's worth of cost savings and are limited in amount (i.e., the aggregate cap), duration (i.e., the limited contract term), and scope (i.e., the total savings that could be achieved from the implementation of any one recommendation were limited by appropriate utilization levels). The payments under the Arrangement do not appear unreasonable, given, among other things, the nature of the actions required of the physicians to have implemented the thirty-six recommended actions, the specificity of the payment formula, and the cap on total remuneration to the Orthopedic Surgery Groups and the Neurosurgery Group.[14] We caution that payments of 50% of cost savings in other arrangements, including multi-year arrangements or arrangements with generalized cost savings formulae, could well lead to a different result.

In light of these circumstances and safeguards, the Arrangement poses a low risk of fraud or abuse under the anti-kickback statute.

III. CONCLUSION

Notwithstanding the foregoing, we reiterate our concerns regarding many arrangements between hospitals and physicians to share cost savings. Improperly designed or implemented arrangements risk adversely affecting patient care and could be vehicles to disguise payments for referrals. For example, an arrangement that cannot be adequately

[14]We are precluded by statute from opining on whether fair market value shall be or was paid for goods, services, or property. See 42 U.S.C. § 1320a-7d(b)(3)(A). While the Requestors have certified that the payments under the Arrangement are consistent with fair market value, we do not rely on that certification in this opinion, nor have we have made an independent fair market value assessment.

and accurately measured for quality of care would pose a high risk of fraud or abuse, as would one that rewards physicians based on overall cost savings without accountability for specific cost reduction measures. Moreover, arrangements structured so as to pose a heightened potential for patient steering and unfair competition would be considered suspect. In short, this opinion is predicated on the specific arrangement posed by the Requestors and is limited to that specific arrangement. Other apparently similar arrangements could raise different concerns and lead to a different result.

Based on the information provided and the totality of the facts described and certified in your request for an advisory opinion and supplemental submissions, we conclude that: (i) the Arrangement constitutes an improper payment to induce reduction or limitation of services pursuant to sections 1128A(b)(1)-(2) of the Act, but that the OIG will not impose sanctions under sections 1128A(b)(1)-(2) on the Requestors in connection with the Arrangement; and (ii) the Arrangement potentially generates prohibited remuneration under the anti-kickback statute, if the requisite intent to induce or reward referrals of Federal health care program business were present, but that the OIG will not impose administrative sanctions on the Requestors under sections 1128(b)(7) or 1128A(a)(7) of the Act (as those sections relate to the commission of acts described in section 1128B(b) of the Act) in connection with the Arrangement.

IV. LIMITATIONS

The limitations applicable to this opinion include the following:

- This advisory opinion is issued only to [names redacted], the requestors of this opinion. This advisory opinion has no application to, and cannot be relied upon by, any other individual or entity.

- This advisory opinion may not be introduced into evidence in any matter involving an entity or individual that is not a requestor to this opinion.

- This advisory opinion is applicable only to the statutory provisions specifically noted above. No opinion is expressed or implied herein with respect to the application of any other Federal, state, or local statute, rule, regulation, ordinance, or other law that may be applicable to the Arrangement, including, without limitation, the physician self-referral law, section 1877 of the Act.

- This advisory opinion will not bind or obligate any agency other than the U.S. Department of Health and Human Services.

- This advisory opinion is limited in scope to the specific arrangement described in this letter and has no applicability to other arrangements, even those that appear similar in nature or scope.

- No opinion is expressed herein regarding the liability of any party under the False Claims Act or other legal authorities for any improper billing, claims submission, cost reporting, or related conduct.

This opinion is also subject to any additional limitations set forth at 42 C.F.R. Part 1008.

The OIG will not proceed against [names redacted] with respect to any action that is part of the Arrangement taken in good faith reliance upon this advisory opinion, as long as all of the material facts have been fully, completely, and accurately presented, and the Arrangement in practice comports with the information provided. The OIG reserves the right to reconsider the questions and issues raised in this advisory opinion and, where the public interest requires, to rescind, modify, or terminate this opinion. In the event that this advisory opinion is modified or terminated, the OIG will not proceed against [names redacted] with respect to any action taken in good faith reliance upon this advisory opinion, where all of the relevant facts were fully, completely, and accurately presented, and where such action was promptly discontinued upon notification of the modification or termination of this advisory opinion. An advisory opinion may be rescinded only if the relevant and material facts have not been fully, completely, and accurately disclosed to the OIG.

Sincerely,

/s/
Lewis Morris
Chief Counsel to the Inspector General

[Appendix A and Distribution List redacted]

[*We redact certain identifying information and certain potentially privileged, confidential, or proprietary information associated with the individual or entity, unless otherwise approved by the requestor.*]

Issued: October 6, 2008

Posted: October 14, 2008

Re: OIG Advisory Opinion No. 08-15

Ladies and Gentlemen:

We are writing in response to your request for an advisory opinion concerning an existing arrangement in which a hospital shares with groups of cardiologists a percentage of the hospital's cost savings arising from the cardiologists' implementation of a number of cost reduction measures in certain procedures (the "Arrangement"). The cost savings are measured based on the cardiologists' use of specific supplies during designated cardiac catheterization laboratory procedures. You have inquired whether the Arrangement constitutes grounds for sanctions arising under: (i) the civil monetary penalty for a hospital's payment to a physician to induce reductions or limitations of services to Medicare or Medicaid beneficiaries under the physician's direct care, sections 1128A(b)(1)-(2) of the Social Security Act (the "Act"); or (ii) the exclusion authority at section 1128(b)(7) of the Act or the civil monetary penalty provision at section 1128A(a)(7) of the Act, as those sections relate to the commission of acts described in section 1128B(b) of the Act, the anti-kickback statute.

You have certified that all of the information provided in your request, including all supplementary letters, is true and correct and constitutes a complete description of the relevant facts and agreements among the parties.

In issuing this opinion, we have relied solely on the facts and information presented to us. We have not undertaken an independent investigation of such information. This opinion is limited to the facts presented. If material facts have not been disclosed or have been misrepresented, this opinion is without force and effect.

Based on the information provided and the totality of the facts as described and certified in your request for an advisory opinion and supplemental submissions, we conclude that: (i) the Arrangement could constitute an improper payment to induce reduction or limitation of services pursuant to sections 1128A(b)(1)-(2) of the Act, but that the Office of Inspector General ("OIG") would not impose sanctions on the requestors of this advisory opinion, [names redacted] (collectively the "Requestors"), in connection with the Arrangement; and (ii) the Arrangement could potentially generate prohibited remuneration under the anti-kickback statute, if the requisite intent to induce or reward referrals of Federal health care program business were present, but that the OIG would not impose administrative sanctions on the Requestors under sections 1128(b)(7) or 1128A(a)(7) of the Act (as those sections relate to the commission of acts described in section 1128B(b) of the Act) in connection with the Arrangement.

This opinion may not be relied on by any persons other than the Requestors and is further qualified as set out in Part IV below and in 42 C.F.R. Part 1008.

I. FACTUAL BACKGROUND

A. Parties

The Hospital. [Name redacted] (the "Hospital") is an acute care hospital in [city and state names redacted] that offers a broad range of inpatient and outpatient hospital services, including cardiac catheterization laboratory services. The Hospital is a participating provider in the Medicare and Medicaid programs.

The Cardiology Groups. [Name redacted] ("Group A") is a limited liability company that employs exclusively cardiologists who are duly licensed in the State of [state name redacted] and have active medical staff privileges at the Hospital. Group A refers patients to the Hospital for inpatient and outpatient hospital services. [Name redacted] ("Group B") is another limited liability company that employs exclusively cardiologists who are duly licensed in the State of [state name redacted] and have active medical staff privileges at the Hospital. Group B also refers patients to the Hospital for inpatient and outpatient hospital services (Group A and Group B are herein referred to, individually, as "a Cardiology Group" and, in combination, as "the Cardiology Groups").[1] The Cardiology Groups perform nearly all of the cardiac catheterization laboratory services at the Hospital. Occasionally a case is completed by another group or by solo practitioners.

[1]Groups A and B both have members who also practice at other hospitals in the region; however, the Hospital is the primary practice location for most of the cardiologists in Groups A and B.

The Program Administrator. The Hospital has engaged [name redacted] (the "Program Administrator") to administer the Arrangement. The Program Administrator collects data and analyzes and manages the Arrangement.[2] The Hospital pays the Program Administrator a monthly fixed fee certified by the Requestors to be fair market value in an arm's-length transaction for services to be provided by the Program Administrator under the Arrangement. The fee is not tied in any way to cost savings or the Cardiology Groups' compensation under the Arrangement.

B. The Arrangement

Under the Arrangement, the Hospital agrees to pay each Cardiology Group a share of three years of cost savings directly attributable to specific changes in that particular group's cardiac catheterization laboratory practices. The Requestors have implemented the three-year Arrangement under which payments are owed to each of the Cardiology Groups at the end of each year (as described in greater detail below). The Cardiology Groups have initiated the specific changes in cardiac catheterization laboratory procedures and the Arrangement is still on-going. The Hospital has not paid amounts owed to the Cardiology Groups under the Arrangement, however, pending the outcome of this opinion.[3] The Requestors have certified that the Hospital will make payments owed under the Arrangement should the Requestors receive a favorable advisory opinion. The Cardiology Groups are the only physician practices participating in the Arrangement.

To develop the Arrangement, the Program Administrator conducted a study of the historic practices of the Cardiology Groups at the Hospital's cardiac catheterization laboratory and identified thirty specific cost savings opportunities. The results of the Program Administrator's study and the specific cost savings opportunities were summarized in a document entitled, "Executive Summary [name redacted] Valueshare for Cardiology" (the "Executive Summary").[4] The Hospital and the Cardiology Groups reviewed the Executive Summary for medical appropriateness and each adopted its recommendations and conclusions.

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[2]The Program Administrator's software product that measures cost, quality, and utilization on a national basis is certified by the American College of Cardiology.

[3]Nonpayment of amounts owed pursuant to a contractual agreement does not, by itself, absolve parties from liability under the fraud and abuse laws.

[4]The Executive Summary is attached to this advisory opinion as Appendix A.

In general, the Executive Summary recommends that the Cardiology Groups change current cardiac catheterization laboratory practices to standardize use of medical devices and supplies and to curb the inappropriate use or waste of medical devices and supplies. The thirty recommendations can be roughly grouped into three categories.

- *Product Standardization.* For the first category, involving twenty-five recommendations, the Executive Summary recommends that the Cardiology Groups standardize the types of cardiac catheterization devices (stents, balloons, interventional guidewires and catheters, vascular closure devices, diagnostic devices, pacemakers and defibrillators) they employ.[5] The Cardiology Groups are required to work in conjunction with the Hospital to evaluate and clinically review vendors and products. The Requestors have certified that they selected the preferred products eligible for payments under the Arrangement based on a process that first considered whether the products were clinically safe and effective. An assessment was then made whether the proposed standardization measures were appropriate on the basis of clinical criteria. Only thereafter did the Requestors consider cost. To the extent costs were a consideration, final selections of vendors and products were made on the basis of prices available to the Hospital for those particular products.

- *"Use as needed" Devices.* The second category, consisting of four recommendations, involves limiting the use of specific vascular closure devices to an "as needed" basis (hereinafter, the "use as needed" recommendations) for coronary and peripheral interventional procedures and diagnostic procedures. The Requestors certified that the cardiologists make patient-by-patient determinations as to whether the devices are clinically indicated, and that any resulting limitation in use of these devices does not adversely affect patient care. The Requestors further certified that the specific vascular closure devices remain readily available in the procedure room.

- *Product Substitution*. The third category involves a single recommendation to substitute, as appropriate, less costly anti-thrombotic medication for other products being used by the cardiologists (hereafter, the "product substitution"). This recommendation may have an appreciable clinical significance. The Requestors certified that the identified product substitution does not adversely impact patient care.

The Arrangement contains several safeguards intended to protect against inappropriate reductions in services. Importantly, in connection with the product standardization, product substitution, and use as needed recommendations, the Requestors certified that the

[5]We note that the Executive Summary identifies with specificity the vendors and products at issue.

individual cardiologists make a patient-by-patient determination of the most appropriate device or supply, and the availability of the full range of devices and supplies is not compromised by the product standardization, product substitution, and use as needed recommendations. The Requestors further certified that individual physicians still have available the same selection of devices and medications after implementation of the Arrangement as before, and that the economies gained through the Arrangement result from inherent clinical and fiscal value and not from restricting the availability of devices and supplies.

With respect to the use as needed recommendations for vascular closure devices, the Arrangement utilizes objective historical and clinical measures reasonably related to the practices and the patient population at the Hospital to establish "floors" beyond which no savings accrue to the Cardiology Groups. For example, according to the Requestors, vascular closure devices for peripheral interventional cases had previously been utilized at the Hospital on 40% of the cases specified under the Arrangement. The Program Administrator determined through analysis of national data that it would be reasonable to reduce the use of vascular closure devices on these cases to 15% of patients and that this reduction would not adversely impact patient care. Thus, the Cardiology Groups receive no share of any savings resulting from the reduction of use of vascular closure devices for peripheral intervention beyond the 15% floor.

For the product substitution, no "floors" were set because substituting usage of the anti-thrombotic medication comported with national guidelines and other quality indicators. However to ensure that this recommendation does not adversely affect the quality of care at the Hospital, the Program Administrator is tracking the Hospital's performance of the covered cardiac procedures against quality indicators established by the American College of Cardiology ("ACC") throughout the base years and contract years. (See infra definitions notes 6 and 7.) According to the Requestors, the ACC quality indicators, against which all of the Arrangement's recommendations were evaluated, reflect objective hospital baselines. The indicators are action-specific and not simply based on isolated patient outcome data unrelated to specific changes in catheterization lab practices. The ACC indicators incorporate enough specificity to permit correlation of outcomes with catheterization lab practices. No cost sharing amounts are allocated to the Cardiology Groups for procedures involving reductions in historical ACC quality indicators.

According to the Program Administrator, if implemented in accordance with the Executive Summary's specifications, the thirty recommendations would present substantial cost savings opportunities for the Hospital without adversely impacting the quality of patient care.

Under the Arrangement, the Hospital intends to pay each of the Cardiology Groups separately for 50% of the yearly savings achieved by the particular group when implementing the thirty recommendations in the Executive Summary. At the end of each year of the three-year Arrangement, cost savings are calculated separately for each group and for each of the thirty recommendations; this precludes shifting of cost savings and ensures that savings generated by utilization beyond the set targets, as applicable, are not credited to the Cardiology Groups.

The sum of all three annual payments to each Cardiology Group, when made, will constitute the entire compensation paid to the particular group for services performed under the contract memorializing the Arrangement between that Cardiology Group and the Hospital. The payment to each Cardiology Group will be calculated using the same formula. For purposes of calculating the payment to each Cardiology Group, the actual costs incurred for the items specified in the thirty recommendations when used by cardiologists in the particular Cardiology Group during the specified procedures (the "current year costs"[6]) are subtracted from the costs for the same items when used during comparable procedures in the respective base year (the "base year costs"[7]). The Requestors are rebasing the Arrangement at the end of each year so that the Cardiology Groups will not receive duplicate payments for savings achieved in prior years. Specifically, at the end of the first year, the Requestors calculated the amounts owed to the Cardiology Groups as described above. The Requestors then reset the base year so that the first year of the Arrangement became the base year for the second year of the Arrangement. The same rebasing will occur for the third year. This annual rebasing method removes earlier accomplished savings from the accounting.

The current year costs for each of the three years are adjusted to account for any inappropriate reductions in the use of items beyond the targets set in the Executive

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[6]The term "current year costs" used here represents the actual costs incurred during each of the three twelve-month periods which comprise the Arrangement. Current year costs were calculated for year one of the Arrangement, recalculated for year two, and will be recalculated again for year three.

[7]Figures for three successive "base years" have been calculated from historical costs during the twelve months immediately preceding the contracts' year one, year two, and year three, respectively. For purposes of this opinion, the Arrangement is limited to the three-year term of the contracts; accordingly, this opinion is without force and effect with respect to any future renewal or extension of the Arrangement. Notwithstanding, we note that any renewal or extension of the Arrangement should incorporate updated current year and base year costs.

Summary. After receipt of a favorable advisory opinion, year-end payments will separately be made to the groups for 50% of the difference between their respective adjusted current year costs and base year costs for the first, second, and third years, if any. Under the Arrangement, the Hospital is obligated to make these aggregate payments to the Cardiology Groups, both of which distribute profits among members on a per capita basis.

Calculation of payments to the Cardiology Groups is subject to the following limitations:

- If a physician's volume of procedures payable by a Federal health care program in the current year exceeds the volume of like procedures payable by a Federal health care program performed in the base year which preceded it, there is no sharing of cost savings for the additional procedures.

- To minimize the cardiologists' financial incentive to steer more costly patients to other hospitals, the case severity, ages, and payors of the patient population treated under the Arrangement are monitored by a committee composed of representatives of the Requestors, using generally-accepted standards. If significant changes from historical measures indicated that a cardiologist had altered his or her referral patterns in a manner beneficial to the Hospital as a result of the Arrangement, the cardiologist at issue would have been terminated from participation in the Arrangement. No cardiologists have been terminated.

- The Executive Summary identified projected cost savings, and the aggregate of payments paid to each Cardiology Group, when made, will not exceed 50% of that group's share of the projected cost savings identified in the initial base year. Each group will be compensated solely for its own savings under the Arrangement.

The Hospital and the Cardiology Groups document the activities and the payment methodology under the Arrangement and will make the documentation available to the Secretary of the United States Department of Health and Human Services, upon request. In addition, the Hospital and the Cardiology Groups disclose the Arrangement to the patients, including the fact that the Cardiology Groups' compensation is based on a percentage of the Hospital's cost savings. The disclosure is made to the patient before the patient is admitted to the Hospital for a procedure covered by the Arrangement; if pre-admission disclosure is impracticable (e.g., the patient is admitted for an unscheduled procedure or the need for the procedure is determined after admission), the disclosure is made before the patient consents to the procedure. The disclosures are in writing, and patients have an opportunity, if they desire, to review details of the Arrangement, including the specific cost savings measures applicable to the patient's procedure.

II. LEGAL ANALYSIS

Programs like the Arrangement are designed to align incentives by offering physicians a portion of a hospital's cost savings in exchange for implementing cost saving strategies. Under the current reimbursement system, the burden of these costs falls on hospitals, not physicians. Payments to physicians based on cost savings may be intended to motivate them to reduce hospital costs associated with procedures performed by physicians at the hospitals.

Properly structured, arrangements that share cost savings can serve legitimate business and medical purposes. Specifically, properly structured arrangements may increase efficiency and reduce waste, thereby potentially increasing a hospital's profitability. However, such arrangements can potentially influence physician judgment to the detriment of patient care. Our concerns include, but are not limited to, the following: (i) stinting on patient care; (ii) "cherry picking" healthy patients and steering sicker (and more costly) patients to hospitals that do not offer such arrangements; (iii) payments in exchange for patient referrals; and (iv) unfair competition (a "race to the bottom") among hospitals offering cost savings programs to foster physician loyalty and to attract more referrals.

Hospital cost savings programs in general, and the Arrangement in particular, may implicate at least three Federal legal authorities: (i) the civil monetary penalty for reductions or limitations of direct patient care services provided to Federal health care program beneficiaries, sections 1128A(b)(1)-(2) of the Act; (ii) the anti-kickback statute, section 1128B(b) of the Act; and (iii) the physician self-referral law, section 1877 of the Act.[8] We address the first two of these authorities; section 1877 of the Act falls outside the scope of the OIG's advisory opinion authority. We express no opinion on the application of section 1877 of the Act to the Arrangement.

A. The Civil Monetary Penalty, Sections 1128A(b)(1)-(2) of the Act

Sections 1128A(b)(1)-(2) of the Act establish a civil monetary penalty ("CMP") against any hospital or critical access hospital that knowingly makes a payment directly or indirectly to a physician (and any physician that receives such a payment) as an inducement to reduce or limit items or services to Medicare or Medicaid beneficiaries under the physician's direct

[8]In addition, nonprofit hospital arrangements raise issues of private inurement and private benefit under the Internal Revenue Service's income tax regulations in connection with section 501(c)(3) of the Internal Revenue Code. See Rev. Rul. 69-383, 1969-2 C.B. 113. We express no opinion on the application of the Internal Revenue Code to the Arrangement.

care. Hospitals that make (and physicians that receive) such payments are liable for CMPs of up to $2,000 per patient covered by the payments. See id. There is no requirement that the prohibited payment be tied to a specific patient or to a reduction in medically necessary care. The CMP applies only to reductions or limitations of items or services provided to Medicare and Medicaid fee-for-service beneficiaries.[9]

The CMP prohibits payments by hospitals to physicians that may induce physicians to reduce or limit items or services furnished to their Medicare and Medicaid patients. A threshold inquiry is whether the Arrangement induces physicians to reduce or limit items or services. Given the specificity of the Arrangement, it is possible to review the opportunities for savings individually and evaluate their potential impact on patient care.

Having reviewed the thirty recommendations, we conclude that the recommendations implicated the CMP. Simply put, with respect to the recommendations under the Arrangement regarding the standardization of devices and supplies, the limitations on the use of vascular closure devices, and product substitution of the anti-thrombotic medication, the Arrangement might induce physicians to reduce or limit the current medical practice at the Hospital. We recognize that the current medical practice may involve care that exceeds the requirements of medical necessity. However, whether the current medical practice reflects necessity or prudence is irrelevant for purposes of the CMP.

In sum, we find that the CMP applies to the recommendations for the standardization of devices, limiting the use of vascular closure devices, and product substitution of the anti-thrombotic medication. Notwithstanding, the Arrangement has several features that, in combination, provide sufficient safeguards so that we would not seek sanctions against the Requestors under sections 1128A(b)(1)-(2) of the Act.

First, the specific cost-saving actions and resulting savings have been clearly and separately identified. The transparency of the Arrangement has allowed for public scrutiny and individual physician accountability for any adverse effects of the Arrangement, including any difference in treatment among patients based on nonclinical indicators. The

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[9]Physician incentive arrangements related to Medicare risk-based managed care contracts, similar Medicaid contracts, and Medicare Advantage plans (formerly Medicare + Choice) are subject to regulation by the Secretary pursuant to sections 1876(i)(8), 1903(m)(2)(A)(x), and 1852(j)(4) of the Act (respectively), in lieu of being subject to sections 1128A(b)(1)-(2). See OIG letter regarding hospital-physician incentive plans for Medicare and Medicaid beneficiaries enrolled in managed care plans (dated August 19, 1999), available at http://oig.hhs.gov/fraud/docs/alertsandbulletins/gsletter.htm. See also 42 C.F.R. § 417.479 (Medicare HMOs or competitive medical plans); 42 C.F.R. § 422.208 (Medicare Advantage plans); 42 C.F.R. § 438.6 (Medicaid risk plans).

transparency of the incentives for specific actions and specific procedures has also facilitated accountability through the medical-legal professional liability system.

Second, the Requestors have proffered credible medical support for the position that implementation of the recommendations does not adversely affect patient care. The Arrangement has been periodically reviewed by the Requestors to confirm that the Arrangement does not have an adverse impact on clinical care.[10]

Third, the amounts to be paid under the Arrangement have been based on all procedures regardless of the patients' insurance coverage, subject to the cap on payment for Federal health care program procedures. Moreover, the procedures to which the Arrangement applies have not been disproportionately performed on Federal health care program beneficiaries. Additionally, the cost savings have been calculated based on the Hospital's actual out-of-pocket acquisition costs, not an accounting convention.

Fourth, the Arrangement has protected against inappropriate reductions in services by utilizing objective historical and clinical measures to establish baseline thresholds beyond which no savings accrue to the Cardiology Groups. The Requestors have certified that these baseline measures have been reasonably related to the Hospital's or comparable hospitals' practices and patient populations. These safeguards have been action-specific and not simply based on isolated patient outcome data unrelated to the specific changes in cardiac catheterization laboratory practices.

Fifth, the product standardization portion of the Arrangement has further protected against inappropriate reductions in services by ensuring that individual physicians still have available the same selection of devices and supplies after implementation of the Arrangement as before. The Arrangement was designed to produce savings through inherent clinical and fiscal value and not from restricting the availability of devices and supplies. As described above, clinical criteria guided the Requestors' process for selecting products to be standardized, and, to the extent cost considerations influenced selections from among products determined to be clinically safe and effective, the cost considerations were limited to prices available to the Hospital for the particular products.

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[10]We have had the Arrangement reviewed by an independent medical expert who has concluded that the cost savings measures, as described in the advisory opinion request and supplemental submissions, should not adversely affect patient care. For purposes of this opinion, however, we rely solely on the Requestors' certifications and nothing in this advisory opinion should be construed as an endorsement or conclusion as to the medical propriety of the specific activities being undertaken as part of the Arrangement.

Sixth, the Hospital and the Cardiology Groups have provided written disclosures of their involvement in the Arrangement to patients whose care might be affected by the Arrangement and have provided patients an opportunity to review the cost savings recommendations prior to admission to the Hospital (or, where pre-admission consent is impracticable, prior to consenting to the procedure). While we do not believe that, standing alone, such disclosures offer sufficient protection from program or patient abuse, effective and meaningful disclosures offer some protection against possible abuses of patient trust.[11]

Seventh, the financial incentives under the Arrangement have been reasonably limited in duration and amount.

Eighth, because each of the Cardiology Groups distributes its profits to its members on a per capita basis, any incentive for an individual cardiologist to generate disproportionate cost savings is mitigated.

Our decision not to impose sanctions on the Requestors in connection with the Arrangement is an exercise of our discretion and is consistent with our Special Advisory Bulletin on "Gainsharing Arrangements and CMPs for Hospital Payments to Physicians to Reduce or Limit Services to Beneficiaries" (July 1999) (the "Special Advisory Bulletin"). We reiterate that the CMP applies to any payment by a hospital to a physician that is intended to induce the reduction or limitation of items or services to Medicare or Medicaid patients under the physician's direct clinical care. The Arrangement is markedly different from "gainsharing" plans that purport to pay physicians a percentage of generalized cost savings not tied to specific, identifiable cost-lowering activities. Importantly, the Arrangement sets out the specific actions to be taken and ties the remuneration to the actual, verifiable cost savings attributable to those actions. This transparency allows an assessment of the likely effect of the Arrangement on quality of care and ensures that the identified actions are the cause of the savings.

"Gainsharing" plans can present substantial risks for both patient and program abuse – risks that are not present in the Arrangement. Given the limited duration and scope of the Arrangement, the safeguards provide sufficient protections against patient and program abuse. Other arrangements, including those that are more expansive in scope or less specific than the Arrangement, are likely to require additional or different safeguards.

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[11]Ordinarily, we would expect patient disclosures to be coupled with patient satisfaction surveys that closely monitor patient perceptions of their care. However, in the context of the Arrangement, which focuses on items and medications used in cardiac catheterization laboratory procedures, we believe that patient satisfaction surveys would not be effective.

B. The Anti-Kickback Statute

The anti-kickback statute makes it a criminal offense knowingly and willfully to offer, pay, solicit, or receive any remuneration to induce or reward referrals of items or services reimbursable by a Federal health care program. See section 1128B(b) of the Act. Where remuneration is paid purposefully to induce or reward referrals of items or services payable by a Federal health care program, the anti-kickback statute is violated. By its terms, the statute ascribes criminal liability to parties on both sides of an impermissible "kickback" transaction. For purposes of the anti-kickback statute, "remuneration" includes the transfer of anything of value, directly or indirectly, overtly or covertly, in cash or in kind.

The statute has been interpreted to cover any arrangement where one purpose of the remuneration was to obtain money for the referral of services or to induce further referrals. United States v. Kats, 871 F.2d 105 (9th Cir. 1989); United States v. Greber, 760 F.2d 68 (3d Cir.), cert. denied, 474 U.S. 988 (1985). Violation of the statute constitutes a felony punishable by a maximum fine of $25,000, imprisonment up to five years, or both. Conviction will also lead to automatic exclusion from Federal health care programs, including Medicare and Medicaid. Where a party commits an act described in section 1128B(b) of the Act, the OIG may initiate administrative proceedings to impose civil monetary penalties on such party under section 1128A(a)(7) of the Act. The OIG may also initiate administrative proceedings to exclude such party from the Federal health care programs under section 1128(b)(7) of the Act.

The Department of Health and Human Services has promulgated safe harbor regulations that define practices that are not subject to the anti-kickback statute because such practices would be unlikely to result in fraud or abuse. See 42 C.F.R. § 1001.952. The safe harbors set forth specific conditions that, if met, assure entities involved of not being prosecuted or sanctioned for the arrangement qualifying for the safe harbor. However, safe harbor protection is afforded only to those arrangements that precisely meet all of the conditions set forth in the safe harbor.

The safe harbor for personal services and management contracts, 42 C.F.R. §1001.952(d), is potentially applicable to the Arrangement. In relevant part for purposes of this advisory opinion, the personal services safe harbor requires that the aggregate compensation paid for the services be set in advance and consistent with fair market value in arm's-length transactions. The Arrangement cannot fit in the safe harbor because the payment to be owed the Cardiology Groups is to be calculated on a percentage basis, and thus the aggregate compensation is not set in advance. However, the absence of safe harbor protection is not fatal. Instead, the Arrangement must be subject to case-by-case evaluation.

Like any compensation arrangement between a hospital and a physician who admits or refers patients to such hospital, we are concerned that the Arrangement could be used to disguise remuneration from the Hospital to reward or induce referrals by the Cardiology Groups. Specifically, the Arrangement could encourage the cardiologists to admit Federal health care program patients to the Hospital, since the cardiologists receive not only their Medicare Part B professional fee, but also, indirectly, a share of the Hospital's payment, depending on cost savings. In other words, the more procedures a cardiologist performs at the Hospital, the more money he or she is likely to receive under the Arrangement.

Multiple-year gainsharing arrangements raise a particular concern, in that they can inappropriately carry over earlier-accomplished savings across years, effectively accounting for them more than once. The resulting unearned duplicate payments can amount to unlawful kickbacks from hospitals to physicians, if accompanied by illicit intent. The annual rebasing method adopted by the Requestors removes earlier accomplished savings from the accounting and thereby avoids improper duplication of physician payments, reducing the accompanying risk of kickbacks.

While we believe the Arrangement could result in illegal remuneration if the requisite intent to induce referrals were present, we will not impose sanctions in the particular circumstances presented here and as qualified below.

First, the circumstances and safeguards of the Arrangement have reduced the likelihood that the Arrangement is being used to attract referring physicians or to increase referrals from existing physicians. Specifically, participation in the Arrangement has been limited to cardiologists already on the medical staff, thus limiting the likelihood that the Arrangement attracts other cardiologists. In addition, the potential savings derived from procedures for Federal health care program beneficiaries have been capped based on the physicians' prior year's admissions of Federal health care program beneficiaries. The period for which payments are calculated has been limited to one year (and the Arrangement is rebased annually as described above), and the overall amount of available cost savings payments over the entire three-year term of the contract has been capped, reducing any incentive to switch facilities. Finally, admissions have been monitored for changes in severity, age, or payor. Thus, while the incentive to refer has not necessarily eliminated, it has been substantially reduced.

Second, the structure of the Arrangement has eliminated the risk that the Arrangement is used to reward cardiologists or other physicians who refer patients to the Cardiology Groups, or their cardiologists. The Cardiology Groups have been the sole participants in the Arrangement and are composed entirely of cardiologists; no surgeons or other physicians are members of the Cardiology Groups or share in their profit distributions. Within the

Cardiology Groups, profits are distributed to their members on a per capita basis, mitigating any incentive for an individual cardiologist to generate disproportionate cost savings.

Third, the Arrangement has set out with specificity the particular actions that generate the cost savings on which the payments are based. The recommendations in the Executive Summary have represented a change in catheterization laboratory practice, for which the cardiologist is responsible and has liability exposure. The product standardization, limitation on use of vascular closure devices, and product substitution have each carried some increased liability risk for the physicians. It is not unreasonable for the cardiologists to receive compensation for the increased risk from the change in practice. Moreover, the payments to be made represent portions of three years' worth of cost savings and have been limited in amount (i.e., the rebasing and aggregate cap), duration (i.e., the limited contract term), and scope (i.e., the total savings that can be achieved from the implementation of any one recommendation are limited by appropriate utilization levels). The payments under the Arrangement do not appear unreasonable, given, among other things, the nature of the actions that have been required of the physicians to implement the thirty recommended actions, the specificity of the payment formula, the annual rebasing, and the cap on total remuneration to the Cardiology Groups.[12] We caution that payments of 50% of cost savings in other arrangements, including multi-year arrangements or arrangements with generalized cost savings formulae, could well lead to a different result.

In light of these circumstances and safeguards, the Arrangement poses a low risk of fraud or abuse under the anti-kickback statute.

III. CONCLUSION

Notwithstanding the foregoing, we reiterate our concerns regarding many arrangements between hospitals and physicians to share cost savings. Improperly designed or implemented arrangements risk adversely affecting patient care and could be vehicles to disguise payments for referrals. For example, an arrangement that cannot be adequately and accurately measured for quality of care would pose a high risk of fraud or abuse, as would one that rewards physicians based on overall cost savings without accountability for specific cost reduction measures. Moreover, arrangements structured so as to pose a heightened potential for patient steering and unfair competition would be considered suspect. In short, this opinion is predicated on the specific arrangement posed by the Requestors and is

[12]We are precluded by statute from opining on whether fair market value shall be or was paid for goods, services, or property. See 42 U.S.C. § 1320a-7d(b)(3)(A). While the Requestors certified that the payments under the Arrangement are consistent with fair market value, we do not rely on that certification in this opinion, nor have we have made an independent fair market value assessment.

limited to that specific arrangement. Other apparently similar arrangements could raise different concerns and lead to a different result.

Based on the information provided and the totality of the facts as described and certified in your request for an advisory opinion and supplemental submissions, we conclude that: (i) the Arrangement could constitute an improper payment to induce reduction or limitation of services pursuant to sections 1128A(b)(1)-(2) of the Act, but that the OIG would not impose sanctions under sections 1128A(b)(1)-(2) on the Requestors in connection with the Arrangement; and (ii) the Arrangement could potentially generate prohibited remuneration under the anti-kickback statute, if the requisite intent to induce or reward referrals of Federal health care program business were present, but that the OIG would not impose administrative sanctions on the Requestors under sections 1128(b)(7) or 1128A(a)(7) of the Act (as those sections relate to the commission of acts described in section 1128B(b) of the Act) in connection with the Arrangement.

IV. LIMITATIONS

The limitations applicable to this opinion include the following:

- This advisory opinion is issued only to [names redacted], the requestors of this opinion. This advisory opinion has no application to, and cannot be relied upon by, any other individual or entity**.**

- This advisory opinion may not be introduced into evidence in any matter involving an entity or individual that is not a requestor to this opinion.

- This advisory opinion is applicable only to the statutory provisions specifically noted above. No opinion is expressed or implied herein with respect to the application of any other Federal, state, or local statute, rule, regulation, ordinance, or other law that may be applicable to the Arrangement, including, without limitation, the physician self-referral law, section 1877 of the Act.

- This advisory opinion will not bind or obligate any agency other than the U.S. Department of Health and Human Services.

- This advisory opinion is limited in scope to the specific arrangement described in this letter and has no applicability to other arrangements, even those that appear similar in nature or scope.

- No opinion is expressed herein regarding the liability of any party under the False Claims Act or other legal authorities for any improper billing, claims submission, cost reporting, or related conduct.

This opinion is also subject to any additional limitations set forth at 42 C.F.R. Part 1008.

The OIG will not proceed against [names redacted] with respect to any action that is part of the Arrangement taken in good faith reliance upon this advisory opinion, as long as all of the material facts have been fully, completely, and accurately presented, and the Arrangement in practice comports with the information provided. The OIG reserves the right to reconsider the questions and issues raised in this advisory opinion and, where the public interest requires, to rescind, modify, or terminate this opinion. In the event that this advisory opinion is modified or terminated, the OIG will not proceed against [names redacted] with respect to any action taken in good faith reliance upon this advisory opinion, where all of the relevant facts were fully, completely, and accurately presented, and where such action was promptly discontinued upon notification of the modification or termination of this advisory opinion. An advisory opinion may be rescinded only if the relevant and material facts have not been fully, completely, and accurately disclosed to the OIG.

Sincerely,

/Lewis Morris/

Lewis Morris
Chief Counsel to the Inspector General

[*We redact certain identifying information and certain potentially privileged, confidential, or proprietary information associated with the individual or entity, unless otherwise approved by the requestor.*]

Issued: October 6, 2008

Posted: October 14, 2008

Re: OIG Advisory Opinion No. 08-15

Ladies and Gentlemen:

We are writing in response to your request for an advisory opinion concerning an existing arrangement in which a hospital shares with groups of cardiologists a percentage of the hospital's cost savings arising from the cardiologists' implementation of a number of cost reduction measures in certain procedures (the "Arrangement"). The cost savings are measured based on the cardiologists' use of specific supplies during designated cardiac catheterization laboratory procedures. You have inquired whether the Arrangement constitutes grounds for sanctions arising under: (i) the civil monetary penalty for a hospital's payment to a physician to induce reductions or limitations of services to Medicare or Medicaid beneficiaries under the physician's direct care, sections 1128A(b)(1)-(2) of the Social Security Act (the "Act"); or (ii) the exclusion authority at section 1128(b)(7) of the Act or the civil monetary penalty provision at section 1128A(a)(7) of the Act, as those sections relate to the commission of acts described in section 1128B(b) of the Act, the anti-kickback statute.

You have certified that all of the information provided in your request, including all supplementary letters, is true and correct and constitutes a complete description of the relevant facts and agreements among the parties.

In issuing this opinion, we have relied solely on the facts and information presented to us. We have not undertaken an independent investigation of such information. This opinion is limited to the facts presented. If material facts have not been disclosed or have been misrepresented, this opinion is without force and effect.

Based on the information provided and the totality of the facts as described and certified in your request for an advisory opinion and supplemental submissions, we conclude that: (i) the Arrangement could constitute an improper payment to induce reduction or limitation of services pursuant to sections 1128A(b)(1)-(2) of the Act, but that the Office of Inspector General ("OIG") would not impose sanctions on the requestors of this advisory opinion, [names redacted] (collectively the "Requestors"), in connection with the Arrangement; and (ii) the Arrangement could potentially generate prohibited remuneration under the anti-kickback statute, if the requisite intent to induce or reward referrals of Federal health care program business were present, but that the OIG would not impose administrative sanctions on the Requestors under sections 1128(b)(7) or 1128A(a)(7) of the Act (as those sections relate to the commission of acts described in section 1128B(b) of the Act) in connection with the Arrangement.

This opinion may not be relied on by any persons other than the Requestors and is further qualified as set out in Part IV below and in 42 C.F.R. Part 1008.

I. FACTUAL BACKGROUND

A. Parties

The Hospital. [Name redacted] (the "Hospital") is an acute care hospital in [city and state names redacted] that offers a broad range of inpatient and outpatient hospital services, including cardiac catheterization laboratory services. The Hospital is a participating provider in the Medicare and Medicaid programs.

The Cardiology Groups. [Name redacted] ("Group A") is a limited liability company that employs exclusively cardiologists who are duly licensed in the State of [state name redacted] and have active medical staff privileges at the Hospital. Group A refers patients to the Hospital for inpatient and outpatient hospital services. [Name redacted] ("Group B") is another limited liability company that employs exclusively cardiologists who are duly licensed in the State of [state name redacted] and have active medical staff privileges at the Hospital. Group B also refers patients to the Hospital for inpatient and outpatient hospital services (Group A and Group B are herein referred to, individually, as "a Cardiology Group" and, in combination, as "the Cardiology Groups").[1] The Cardiology Groups perform nearly all of the cardiac catheterization laboratory services at the Hospital. Occasionally a case is completed by another group or by solo practitioners.

[1]Groups A and B both have members who also practice at other hospitals in the region; however, the Hospital is the primary practice location for most of the cardiologists in Groups A and B.

The Program Administrator. The Hospital has engaged [name redacted] (the "Program Administrator") to administer the Arrangement. The Program Administrator collects data and analyzes and manages the Arrangement.[2] The Hospital pays the Program Administrator a monthly fixed fee certified by the Requestors to be fair market value in an arm's-length transaction for services to be provided by the Program Administrator under the Arrangement. The fee is not tied in any way to cost savings or the Cardiology Groups' compensation under the Arrangement.

B. The Arrangement

Under the Arrangement, the Hospital agrees to pay each Cardiology Group a share of three years of cost savings directly attributable to specific changes in that particular group's cardiac catheterization laboratory practices. The Requestors have implemented the three-year Arrangement under which payments are owed to each of the Cardiology Groups at the end of each year (as described in greater detail below). The Cardiology Groups have initiated the specific changes in cardiac catheterization laboratory procedures and the Arrangement is still on-going. The Hospital has not paid amounts owed to the Cardiology Groups under the Arrangement, however, pending the outcome of this opinion.[3] The Requestors have certified that the Hospital will make payments owed under the Arrangement should the Requestors receive a favorable advisory opinion. The Cardiology Groups are the only physician practices participating in the Arrangement.

To develop the Arrangement, the Program Administrator conducted a study of the historic practices of the Cardiology Groups at the Hospital's cardiac catheterization laboratory and identified thirty specific cost savings opportunities. The results of the Program Administrator's study and the specific cost savings opportunities were summarized in a document entitled, "Executive Summary [name redacted] Valueshare for Cardiology" (the "Executive Summary").[4] The Hospital and the Cardiology Groups reviewed the Executive Summary for medical appropriateness and each adopted its recommendations and conclusions.

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[2]The Program Administrator's software product that measures cost, quality, and utilization on a national basis is certified by the American College of Cardiology.

[3]Nonpayment of amounts owed pursuant to a contractual agreement does not, by itself, absolve parties from liability under the fraud and abuse laws.

[4]The Executive Summary is attached to this advisory opinion as Appendix A.

In general, the Executive Summary recommends that the Cardiology Groups change current cardiac catheterization laboratory practices to standardize use of medical devices and supplies and to curb the inappropriate use or waste of medical devices and supplies. The thirty recommendations can be roughly grouped into three categories.

- *Product Standardization.* For the first category, involving twenty-five recommendations, the Executive Summary recommends that the Cardiology Groups standardize the types of cardiac catheterization devices (stents, balloons, interventional guidewires and catheters, vascular closure devices, diagnostic devices, pacemakers and defibrillators) they employ.[5] The Cardiology Groups are required to work in conjunction with the Hospital to evaluate and clinically review vendors and products. The Requestors have certified that they selected the preferred products eligible for payments under the Arrangement based on a process that first considered whether the products were clinically safe and effective. An assessment was then made whether the proposed standardization measures were appropriate on the basis of clinical criteria. Only thereafter did the Requestors consider cost. To the extent costs were a consideration, final selections of vendors and products were made on the basis of prices available to the Hospital for those particular products.

- *"Use as needed" Devices.* The second category, consisting of four recommendations, involves limiting the use of specific vascular closure devices to an "as needed" basis (hereinafter, the "use as needed" recommendations) for coronary and peripheral interventional procedures and diagnostic procedures. The Requestors certified that the cardiologists make patient-by-patient determinations as to whether the devices are clinically indicated, and that any resulting limitation in use of these devices does not adversely affect patient care. The Requestors further certified that the specific vascular closure devices remain readily available in the procedure room.

- *Product Substitution*. The third category involves a single recommendation to substitute, as appropriate, less costly anti-thrombotic medication for other products being used by the cardiologists (hereafter, the "product substitution"). This recommendation may have an appreciable clinical significance. The Requestors certified that the identified product substitution does not adversely impact patient care.

The Arrangement contains several safeguards intended to protect against inappropriate reductions in services. Importantly, in connection with the product standardization, product substitution, and use as needed recommendations, the Requestors certified that the

[5]We note that the Executive Summary identifies with specificity the vendors and products at issue.

individual cardiologists make a patient-by-patient determination of the most appropriate device or supply, and the availability of the full range of devices and supplies is not compromised by the product standardization, product substitution, and use as needed recommendations. The Requestors further certified that individual physicians still have available the same selection of devices and medications after implementation of the Arrangement as before, and that the economies gained through the Arrangement result from inherent clinical and fiscal value and not from restricting the availability of devices and supplies.

With respect to the use as needed recommendations for vascular closure devices, the Arrangement utilizes objective historical and clinical measures reasonably related to the practices and the patient population at the Hospital to establish "floors" beyond which no savings accrue to the Cardiology Groups. For example, according to the Requestors, vascular closure devices for peripheral interventional cases had previously been utilized at the Hospital on 40% of the cases specified under the Arrangement. The Program Administrator determined through analysis of national data that it would be reasonable to reduce the use of vascular closure devices on these cases to 15% of patients and that this reduction would not adversely impact patient care. Thus, the Cardiology Groups receive no share of any savings resulting from the reduction of use of vascular closure devices for peripheral intervention beyond the 15% floor.

For the product substitution, no "floors" were set because substituting usage of the anti-thrombotic medication comported with national guidelines and other quality indicators. However to ensure that this recommendation does not adversely affect the quality of care at the Hospital, the Program Administrator is tracking the Hospital's performance of the covered cardiac procedures against quality indicators established by the American College of Cardiology ("ACC") throughout the base years and contract years. (See infra definitions notes 6 and 7.) According to the Requestors, the ACC quality indicators, against which all of the Arrangement's recommendations were evaluated, reflect objective hospital baselines. The indicators are action-specific and not simply based on isolated patient outcome data unrelated to specific changes in catheterization lab practices. The ACC indicators incorporate enough specificity to permit correlation of outcomes with catheterization lab practices. No cost sharing amounts are allocated to the Cardiology Groups for procedures involving reductions in historical ACC quality indicators.

According to the Program Administrator, if implemented in accordance with the Executive Summary's specifications, the thirty recommendations would present substantial cost savings opportunities for the Hospital without adversely impacting the quality of patient care.

Under the Arrangement, the Hospital intends to pay each of the Cardiology Groups separately for 50% of the yearly savings achieved by the particular group when implementing the thirty recommendations in the Executive Summary. At the end of each year of the three-year Arrangement, cost savings are calculated separately for each group and for each of the thirty recommendations; this precludes shifting of cost savings and ensures that savings generated by utilization beyond the set targets, as applicable, are not credited to the Cardiology Groups.

The sum of all three annual payments to each Cardiology Group, when made, will constitute the entire compensation paid to the particular group for services performed under the contract memorializing the Arrangement between that Cardiology Group and the Hospital. The payment to each Cardiology Group will be calculated using the same formula. For purposes of calculating the payment to each Cardiology Group, the actual costs incurred for the items specified in the thirty recommendations when used by cardiologists in the particular Cardiology Group during the specified procedures (the "current year costs"[6]) are subtracted from the costs for the same items when used during comparable procedures in the respective base year (the "base year costs"[7]). The Requestors are rebasing the Arrangement at the end of each year so that the Cardiology Groups will not receive duplicate payments for savings achieved in prior years. Specifically, at the end of the first year, the Requestors calculated the amounts owed to the Cardiology Groups as described above. The Requestors then reset the base year so that the first year of the Arrangement became the base year for the second year of the Arrangement. The same rebasing will occur for the third year. This annual rebasing method removes earlier accomplished savings from the accounting.

The current year costs for each of the three years are adjusted to account for any inappropriate reductions in the use of items beyond the targets set in the Executive

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[6]The term "current year costs" used here represents the actual costs incurred during each of the three twelve-month periods which comprise the Arrangement. Current year costs were calculated for year one of the Arrangement, recalculated for year two, and will be recalculated again for year three.

[7]Figures for three successive "base years" have been calculated from historical costs during the twelve months immediately preceding the contracts' year one, year two, and year three, respectively. For purposes of this opinion, the Arrangement is limited to the three-year term of the contracts; accordingly, this opinion is without force and effect with respect to any future renewal or extension of the Arrangement. Notwithstanding, we note that any renewal or extension of the Arrangement should incorporate updated current year and base year costs.

Summary. After receipt of a favorable advisory opinion, year-end payments will separately be made to the groups for 50% of the difference between their respective adjusted current year costs and base year costs for the first, second, and third years, if any. Under the Arrangement, the Hospital is obligated to make these aggregate payments to the Cardiology Groups, both of which distribute profits among members on a per capita basis.

Calculation of payments to the Cardiology Groups is subject to the following limitations:

- If a physician's volume of procedures payable by a Federal health care program in the current year exceeds the volume of like procedures payable by a Federal health care program performed in the base year which preceded it, there is no sharing of cost savings for the additional procedures.

- To minimize the cardiologists' financial incentive to steer more costly patients to other hospitals, the case severity, ages, and payors of the patient population treated under the Arrangement are monitored by a committee composed of representatives of the Requestors, using generally-accepted standards. If significant changes from historical measures indicated that a cardiologist had altered his or her referral patterns in a manner beneficial to the Hospital as a result of the Arrangement, the cardiologist at issue would have been terminated from participation in the Arrangement. No cardiologists have been terminated.

- The Executive Summary identified projected cost savings, and the aggregate of payments paid to each Cardiology Group, when made, will not exceed 50% of that group's share of the projected cost savings identified in the initial base year. Each group will be compensated solely for its own savings under the Arrangement.

The Hospital and the Cardiology Groups document the activities and the payment methodology under the Arrangement and will make the documentation available to the Secretary of the United States Department of Health and Human Services, upon request. In addition, the Hospital and the Cardiology Groups disclose the Arrangement to the patients, including the fact that the Cardiology Groups' compensation is based on a percentage of the Hospital's cost savings. The disclosure is made to the patient before the patient is admitted to the Hospital for a procedure covered by the Arrangement; if pre-admission disclosure is impracticable (e.g., the patient is admitted for an unscheduled procedure or the need for the procedure is determined after admission), the disclosure is made before the patient consents to the procedure. The disclosures are in writing, and patients have an opportunity, if they desire, to review details of the Arrangement, including the specific cost savings measures applicable to the patient's procedure.

II. LEGAL ANALYSIS

Programs like the Arrangement are designed to align incentives by offering physicians a portion of a hospital's cost savings in exchange for implementing cost saving strategies. Under the current reimbursement system, the burden of these costs falls on hospitals, not physicians. Payments to physicians based on cost savings may be intended to motivate them to reduce hospital costs associated with procedures performed by physicians at the hospitals.

Properly structured, arrangements that share cost savings can serve legitimate business and medical purposes. Specifically, properly structured arrangements may increase efficiency and reduce waste, thereby potentially increasing a hospital's profitability. However, such arrangements can potentially influence physician judgment to the detriment of patient care. Our concerns include, but are not limited to, the following: (i) stinting on patient care; (ii) "cherry picking" healthy patients and steering sicker (and more costly) patients to hospitals that do not offer such arrangements; (iii) payments in exchange for patient referrals; and (iv) unfair competition (a "race to the bottom") among hospitals offering cost savings programs to foster physician loyalty and to attract more referrals.

Hospital cost savings programs in general, and the Arrangement in particular, may implicate at least three Federal legal authorities: (i) the civil monetary penalty for reductions or limitations of direct patient care services provided to Federal health care program beneficiaries, sections 1128A(b)(1)-(2) of the Act; (ii) the anti-kickback statute, section 1128B(b) of the Act; and (iii) the physician self-referral law, section 1877 of the Act.[8] We address the first two of these authorities; section 1877 of the Act falls outside the scope of the OIG's advisory opinion authority. We express no opinion on the application of section 1877 of the Act to the Arrangement.

A. The Civil Monetary Penalty, Sections 1128A(b)(1)-(2) of the Act

Sections 1128A(b)(1)-(2) of the Act establish a civil monetary penalty ("CMP") against any hospital or critical access hospital that knowingly makes a payment directly or indirectly to a physician (and any physician that receives such a payment) as an inducement to reduce or limit items or services to Medicare or Medicaid beneficiaries under the physician's direct

[8]In addition, nonprofit hospital arrangements raise issues of private inurement and private benefit under the Internal Revenue Service's income tax regulations in connection with section 501(c)(3) of the Internal Revenue Code. See Rev. Rul. 69-383, 1969-2 C.B. 113. We express no opinion on the application of the Internal Revenue Code to the Arrangement.

care. Hospitals that make (and physicians that receive) such payments are liable for CMPs of up to $2,000 per patient covered by the payments. See id. There is no requirement that the prohibited payment be tied to a specific patient or to a reduction in medically necessary care. The CMP applies only to reductions or limitations of items or services provided to Medicare and Medicaid fee-for-service beneficiaries.[9]

The CMP prohibits payments by hospitals to physicians that may induce physicians to reduce or limit items or services furnished to their Medicare and Medicaid patients. A threshold inquiry is whether the Arrangement induces physicians to reduce or limit items or services. Given the specificity of the Arrangement, it is possible to review the opportunities for savings individually and evaluate their potential impact on patient care.

Having reviewed the thirty recommendations, we conclude that the recommendations implicated the CMP. Simply put, with respect to the recommendations under the Arrangement regarding the standardization of devices and supplies, the limitations on the use of vascular closure devices, and product substitution of the anti-thrombotic medication, the Arrangement might induce physicians to reduce or limit the current medical practice at the Hospital. We recognize that the current medical practice may involve care that exceeds the requirements of medical necessity. However, whether the current medical practice reflects necessity or prudence is irrelevant for purposes of the CMP.

In sum, we find that the CMP applies to the recommendations for the standardization of devices, limiting the use of vascular closure devices, and product substitution of the anti-thrombotic medication. Notwithstanding, the Arrangement has several features that, in combination, provide sufficient safeguards so that we would not seek sanctions against the Requestors under sections 1128A(b)(1)-(2) of the Act.

First, the specific cost-saving actions and resulting savings have been clearly and separately identified. The transparency of the Arrangement has allowed for public scrutiny and individual physician accountability for any adverse effects of the Arrangement, including any difference in treatment among patients based on nonclinical indicators. The

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[9]Physician incentive arrangements related to Medicare risk-based managed care contracts, similar Medicaid contracts, and Medicare Advantage plans (formerly Medicare + Choice) are subject to regulation by the Secretary pursuant to sections 1876(i)(8), 1903(m)(2)(A)(x), and 1852(j)(4) of the Act (respectively), in lieu of being subject to sections 1128A(b)(1)-(2). See OIG letter regarding hospital-physician incentive plans for Medicare and Medicaid beneficiaries enrolled in managed care plans (dated August 19, 1999), available at http://oig.hhs.gov/fraud/docs/alertsandbulletins/gsletter.htm. See also 42 C.F.R. § 417.479 (Medicare HMOs or competitive medical plans); 42 C.F.R. § 422.208 (Medicare Advantage plans); 42 C.F.R. § 438.6 (Medicaid risk plans).

transparency of the incentives for specific actions and specific procedures has also facilitated accountability through the medical-legal professional liability system.

Second, the Requestors have proffered credible medical support for the position that implementation of the recommendations does not adversely affect patient care. The Arrangement has been periodically reviewed by the Requestors to confirm that the Arrangement does not have an adverse impact on clinical care.[10]

Third, the amounts to be paid under the Arrangement have been based on all procedures regardless of the patients' insurance coverage, subject to the cap on payment for Federal health care program procedures. Moreover, the procedures to which the Arrangement applies have not been disproportionately performed on Federal health care program beneficiaries. Additionally, the cost savings have been calculated based on the Hospital's actual out-of-pocket acquisition costs, not an accounting convention.

Fourth, the Arrangement has protected against inappropriate reductions in services by utilizing objective historical and clinical measures to establish baseline thresholds beyond which no savings accrue to the Cardiology Groups. The Requestors have certified that these baseline measures have been reasonably related to the Hospital's or comparable hospitals' practices and patient populations. These safeguards have been action-specific and not simply based on isolated patient outcome data unrelated to the specific changes in cardiac catheterization laboratory practices.

Fifth, the product standardization portion of the Arrangement has further protected against inappropriate reductions in services by ensuring that individual physicians still have available the same selection of devices and supplies after implementation of the Arrangement as before. The Arrangement was designed to produce savings through inherent clinical and fiscal value and not from restricting the availability of devices and supplies. As described above, clinical criteria guided the Requestors' process for selecting products to be standardized, and, to the extent cost considerations influenced selections from among products determined to be clinically safe and effective, the cost considerations were limited to prices available to the Hospital for the particular products.

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[10]We have had the Arrangement reviewed by an independent medical expert who has concluded that the cost savings measures, as described in the advisory opinion request and supplemental submissions, should not adversely affect patient care. For purposes of this opinion, however, we rely solely on the Requestors' certifications and nothing in this advisory opinion should be construed as an endorsement or conclusion as to the medical propriety of the specific activities being undertaken as part of the Arrangement.

Sixth, the Hospital and the Cardiology Groups have provided written disclosures of their involvement in the Arrangement to patients whose care might be affected by the Arrangement and have provided patients an opportunity to review the cost savings recommendations prior to admission to the Hospital (or, where pre-admission consent is impracticable, prior to consenting to the procedure). While we do not believe that, standing alone, such disclosures offer sufficient protection from program or patient abuse, effective and meaningful disclosures offer some protection against possible abuses of patient trust.[11]

Seventh, the financial incentives under the Arrangement have been reasonably limited in duration and amount.

Eighth, because each of the Cardiology Groups distributes its profits to its members on a per capita basis, any incentive for an individual cardiologist to generate disproportionate cost savings is mitigated.

Our decision not to impose sanctions on the Requestors in connection with the Arrangement is an exercise of our discretion and is consistent with our Special Advisory Bulletin on "Gainsharing Arrangements and CMPs for Hospital Payments to Physicians to Reduce or Limit Services to Beneficiaries" (July 1999) (the "Special Advisory Bulletin"). We reiterate that the CMP applies to any payment by a hospital to a physician that is intended to induce the reduction or limitation of items or services to Medicare or Medicaid patients under the physician's direct clinical care. The Arrangement is markedly different from "gainsharing" plans that purport to pay physicians a percentage of generalized cost savings not tied to specific, identifiable cost-lowering activities. Importantly, the Arrangement sets out the specific actions to be taken and ties the remuneration to the actual, verifiable cost savings attributable to those actions. This transparency allows an assessment of the likely effect of the Arrangement on quality of care and ensures that the identified actions are the cause of the savings.

"Gainsharing" plans can present substantial risks for both patient and program abuse – risks that are not present in the Arrangement. Given the limited duration and scope of the Arrangement, the safeguards provide sufficient protections against patient and program abuse. Other arrangements, including those that are more expansive in scope or less specific than the Arrangement, are likely to require additional or different safeguards.

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[11]Ordinarily, we would expect patient disclosures to be coupled with patient satisfaction surveys that closely monitor patient perceptions of their care. However, in the context of the Arrangement, which focuses on items and medications used in cardiac catheterization laboratory procedures, we believe that patient satisfaction surveys would not be effective.

B. The Anti-Kickback Statute

The anti-kickback statute makes it a criminal offense knowingly and willfully to offer, pay, solicit, or receive any remuneration to induce or reward referrals of items or services reimbursable by a Federal health care program. See section 1128B(b) of the Act. Where remuneration is paid purposefully to induce or reward referrals of items or services payable by a Federal health care program, the anti-kickback statute is violated. By its terms, the statute ascribes criminal liability to parties on both sides of an impermissible "kickback" transaction. For purposes of the anti-kickback statute, "remuneration" includes the transfer of anything of value, directly or indirectly, overtly or covertly, in cash or in kind.

The statute has been interpreted to cover any arrangement where one purpose of the remuneration was to obtain money for the referral of services or to induce further referrals. United States v. Kats, 871 F.2d 105 (9th Cir. 1989); United States v. Greber, 760 F.2d 68 (3d Cir.), cert. denied, 474 U.S. 988 (1985). Violation of the statute constitutes a felony punishable by a maximum fine of $25,000, imprisonment up to five years, or both. Conviction will also lead to automatic exclusion from Federal health care programs, including Medicare and Medicaid. Where a party commits an act described in section 1128B(b) of the Act, the OIG may initiate administrative proceedings to impose civil monetary penalties on such party under section 1128A(a)(7) of the Act. The OIG may also initiate administrative proceedings to exclude such party from the Federal health care programs under section 1128(b)(7) of the Act.

The Department of Health and Human Services has promulgated safe harbor regulations that define practices that are not subject to the anti-kickback statute because such practices would be unlikely to result in fraud or abuse. See 42 C.F.R. § 1001.952. The safe harbors set forth specific conditions that, if met, assure entities involved of not being prosecuted or sanctioned for the arrangement qualifying for the safe harbor. However, safe harbor protection is afforded only to those arrangements that precisely meet all of the conditions set forth in the safe harbor.

The safe harbor for personal services and management contracts, 42 C.F.R. §1001.952(d), is potentially applicable to the Arrangement. In relevant part for purposes of this advisory opinion, the personal services safe harbor requires that the aggregate compensation paid for the services be set in advance and consistent with fair market value in arm's-length transactions. The Arrangement cannot fit in the safe harbor because the payment to be owed the Cardiology Groups is to be calculated on a percentage basis, and thus the aggregate compensation is not set in advance. However, the absence of safe harbor protection is not fatal. Instead, the Arrangement must be subject to case-by-case evaluation.

Like any compensation arrangement between a hospital and a physician who admits or refers patients to such hospital, we are concerned that the Arrangement could be used to disguise remuneration from the Hospital to reward or induce referrals by the Cardiology Groups. Specifically, the Arrangement could encourage the cardiologists to admit Federal health care program patients to the Hospital, since the cardiologists receive not only their Medicare Part B professional fee, but also, indirectly, a share of the Hospital's payment, depending on cost savings. In other words, the more procedures a cardiologist performs at the Hospital, the more money he or she is likely to receive under the Arrangement.

Multiple-year gainsharing arrangements raise a particular concern, in that they can inappropriately carry over earlier-accomplished savings across years, effectively accounting for them more than once. The resulting unearned duplicate payments can amount to unlawful kickbacks from hospitals to physicians, if accompanied by illicit intent. The annual rebasing method adopted by the Requestors removes earlier accomplished savings from the accounting and thereby avoids improper duplication of physician payments, reducing the accompanying risk of kickbacks.

While we believe the Arrangement could result in illegal remuneration if the requisite intent to induce referrals were present, we will not impose sanctions in the particular circumstances presented here and as qualified below.

First, the circumstances and safeguards of the Arrangement have reduced the likelihood that the Arrangement is being used to attract referring physicians or to increase referrals from existing physicians. Specifically, participation in the Arrangement has been limited to cardiologists already on the medical staff, thus limiting the likelihood that the Arrangement attracts other cardiologists. In addition, the potential savings derived from procedures for Federal health care program beneficiaries have been capped based on the physicians' prior year's admissions of Federal health care program beneficiaries. The period for which payments are calculated has been limited to one year (and the Arrangement is rebased annually as described above), and the overall amount of available cost savings payments over the entire three-year term of the contract has been capped, reducing any incentive to switch facilities. Finally, admissions have been monitored for changes in severity, age, or payor. Thus, while the incentive to refer has not necessarily eliminated, it has been substantially reduced.

Second, the structure of the Arrangement has eliminated the risk that the Arrangement is used to reward cardiologists or other physicians who refer patients to the Cardiology Groups, or their cardiologists. The Cardiology Groups have been the sole participants in the Arrangement and are composed entirely of cardiologists; no surgeons or other physicians are members of the Cardiology Groups or share in their profit distributions. Within the

Cardiology Groups, profits are distributed to their members on a per capita basis, mitigating any incentive for an individual cardiologist to generate disproportionate cost savings.

Third, the Arrangement has set out with specificity the particular actions that generate the cost savings on which the payments are based. The recommendations in the Executive Summary have represented a change in catheterization laboratory practice, for which the cardiologist is responsible and has liability exposure. The product standardization, limitation on use of vascular closure devices, and product substitution have each carried some increased liability risk for the physicians. It is not unreasonable for the cardiologists to receive compensation for the increased risk from the change in practice. Moreover, the payments to be made represent portions of three years' worth of cost savings and have been limited in amount (i.e., the rebasing and aggregate cap), duration (i.e., the limited contract term), and scope (i.e., the total savings that can be achieved from the implementation of any one recommendation are limited by appropriate utilization levels). The payments under the Arrangement do not appear unreasonable, given, among other things, the nature of the actions that have been required of the physicians to implement the thirty recommended actions, the specificity of the payment formula, the annual rebasing, and the cap on total remuneration to the Cardiology Groups.[12] We caution that payments of 50% of cost savings in other arrangements, including multi-year arrangements or arrangements with generalized cost savings formulae, could well lead to a different result.

In light of these circumstances and safeguards, the Arrangement poses a low risk of fraud or abuse under the anti-kickback statute.

III. CONCLUSION

Notwithstanding the foregoing, we reiterate our concerns regarding many arrangements between hospitals and physicians to share cost savings. Improperly designed or implemented arrangements risk adversely affecting patient care and could be vehicles to disguise payments for referrals. For example, an arrangement that cannot be adequately and accurately measured for quality of care would pose a high risk of fraud or abuse, as would one that rewards physicians based on overall cost savings without accountability for specific cost reduction measures. Moreover, arrangements structured so as to pose a heightened potential for patient steering and unfair competition would be considered suspect. In short, this opinion is predicated on the specific arrangement posed by the Requestors and is

[12]We are precluded by statute from opining on whether fair market value shall be or was paid for goods, services, or property. See 42 U.S.C. § 1320a-7d(b)(3)(A). While the Requestors certified that the payments under the Arrangement are consistent with fair market value, we do not rely on that certification in this opinion, nor have we have made an independent fair market value assessment.

limited to that specific arrangement. Other apparently similar arrangements could raise different concerns and lead to a different result.

Based on the information provided and the totality of the facts as described and certified in your request for an advisory opinion and supplemental submissions, we conclude that: (i) the Arrangement could constitute an improper payment to induce reduction or limitation of services pursuant to sections 1128A(b)(1)-(2) of the Act, but that the OIG would not impose sanctions under sections 1128A(b)(1)-(2) on the Requestors in connection with the Arrangement; and (ii) the Arrangement could potentially generate prohibited remuneration under the anti-kickback statute, if the requisite intent to induce or reward referrals of Federal health care program business were present, but that the OIG would not impose administrative sanctions on the Requestors under sections 1128(b)(7) or 1128A(a)(7) of the Act (as those sections relate to the commission of acts described in section 1128B(b) of the Act) in connection with the Arrangement.

IV. LIMITATIONS

The limitations applicable to this opinion include the following:

- This advisory opinion is issued only to [names redacted], the requestors of this opinion. This advisory opinion has no application to, and cannot be relied upon by, any other individual or entity**.**

- This advisory opinion may not be introduced into evidence in any matter involving an entity or individual that is not a requestor to this opinion.

- This advisory opinion is applicable only to the statutory provisions specifically noted above. No opinion is expressed or implied herein with respect to the application of any other Federal, state, or local statute, rule, regulation, ordinance, or other law that may be applicable to the Arrangement, including, without limitation, the physician self-referral law, section 1877 of the Act.

- This advisory opinion will not bind or obligate any agency other than the U.S. Department of Health and Human Services.

- This advisory opinion is limited in scope to the specific arrangement described in this letter and has no applicability to other arrangements, even those that appear similar in nature or scope.

- No opinion is expressed herein regarding the liability of any party under the False Claims Act or other legal authorities for any improper billing, claims submission, cost reporting, or related conduct.

This opinion is also subject to any additional limitations set forth at 42 C.F.R. Part 1008.

The OIG will not proceed against [names redacted] with respect to any action that is part of the Arrangement taken in good faith reliance upon this advisory opinion, as long as all of the material facts have been fully, completely, and accurately presented, and the Arrangement in practice comports with the information provided. The OIG reserves the right to reconsider the questions and issues raised in this advisory opinion and, where the public interest requires, to rescind, modify, or terminate this opinion. In the event that this advisory opinion is modified or terminated, the OIG will not proceed against [names redacted] with respect to any action taken in good faith reliance upon this advisory opinion, where all of the relevant facts were fully, completely, and accurately presented, and where such action was promptly discontinued upon notification of the modification or termination of this advisory opinion. An advisory opinion may be rescinded only if the relevant and material facts have not been fully, completely, and accurately disclosed to the OIG.

Sincerely,

/Lewis Morris/

Lewis Morris
Chief Counsel to the Inspector General

[*We redact certain identifying information and certain potentially privileged, confidential, or proprietary information associated with the individual or entity, unless otherwise approved by the requestor.*]

Issued: November 25, 2008

Posted: December 8, 2008

To: Attached Distribution List

Re: OIG Advisory Opinion No. 08-21

Ladies & Gentlemen:

We are writing in response to your request for an advisory opinion concerning an existing arrangement in which a hospital has agreed to share with four cardiology groups and one radiology group a percentage of the hospital's cost savings arising from the physicians' implementation over two years of a number of cost reduction measures in certain cardiac catheterization procedures[1] (the "Arrangement"). The cost savings are measured based on the physicians' use of specific medical devices and supplies during designated cardiac catheterization procedures. You have inquired whether the Arrangement constitutes grounds for sanctions arising under: (i) the civil monetary penalty for a hospital's payment to a physician to induce reduction or limitation of services to Medicare or Medicaid beneficiaries under the physician's direct care, sections 1128A(b)(1)-(2) of the Social Security Act (the "Act"); or (ii) the exclusion authority at section 1128(b)(7) of the Act or the civil monetary penalty provision at section 1128A(a)(7) of the Act, as those sections relate to the commission of acts described in section 1128B(b) of the Act, the anti-kickback statute.

[1]We note that the request refers to cardiac catheterization laboratory and special procedures laboratory procedures, services, practices, etc. For purposes of this opinion, we will refer to them collectively as "cardiac catheterization" procedures, services, practices, etc.

You have certified that all of the information provided in your request, including all supplementary letters, is true and correct and constitutes a complete description of the relevant facts and agreements among the parties.

In issuing this opinion, we have relied solely on the facts and information presented to us. We have not undertaken an independent investigation of such information. This opinion is limited to the facts presented. If material facts have not been disclosed or have been misrepresented, this opinion is without force and effect.

Based on the information provided and the totality of the facts as described and certified in your request for an advisory opinion and supplemental submissions, we conclude that: (i) the Arrangement could constitute an improper payment to induce reduction or limitation of services pursuant to sections 1128A(b)(1)-(2) of the Act, but that the Office of Inspector General ("OIG") would not impose sanctions on the requestors of this advisory opinion, [names redacted] (collectively, the "Requestors"), in connection with the Arrangement; and (ii) the Arrangement could potentially generate prohibited remuneration under the anti-kickback statute, if the requisite intent to induce or reward referrals of Federal health care program business were present, but that the OIG would not impose administrative sanctions on the Requestors under sections 1128(b)(7) or 1128A(a)(7) of the Act (as those sections relate to the commission of acts described in section 1128B(b) of the Act) in connection with the Arrangement.

This opinion may not be relied on by any persons other than the Requestors and is further qualified as set out in Part IV below and in 42 C.F.R. Part 1008.

I. FACTUAL BACKGROUND

A. Parties

The Hospital. [Name redacted] (the "Hospital") is an acute care hospital in [city and state names redacted] that offers a broad range of inpatient and outpatient hospital services, including cardiac catheterization services. The Hospital is a participating provider in the Medicare and Medicaid programs.

The Cardiology Groups. [Name redacted] is a limited liability company that employs exclusively cardiologists who are duly licensed in the State of [state name redacted] and have active medical staff privileges at the Hospital. [Name redacted] is a limited liability company that employs exclusively cardiologists who are duly licensed in the State of [state name redacted] and have active medical staff privileges at the Hospital. [Name redacted] is a professional medical corporation that employs exclusively cardiologists who are duly licensed in the State of [state name redacted] and have active medical staff privileges at the

Hospital. [Name redacted] is a professional medical corporation that employs exclusively cardiologists who are duly licensed in the State of [state name redacted] who have active medical staff privileges at the Hospital. These practice groups are herein referred to, individually, as a "Cardiology Group" and, in combination, as the "Cardiology Groups." The Cardiology Groups refer patients to the Hospital for inpatient and outpatient hospital services. Each Cardiology Group entered into a separate contract with the Hospital that set forth the projected savings opportunities available to that practice.

The Radiology Group. [Name redacted] (the "Radiology Group") is a limited liability company that employs exclusively interventional radiologists who are duly licensed in the State of [state name redacted] and have active medical staff privileges at the Hospital. The Radiology Group refers patients to the Hospital for inpatient and outpatient hospital services. The Radiology Group entered into a separate contract with the Hospital that set forth the projected savings opportunities available to the practice.

In combination, the Cardiology Groups and the Radiology Group, herein referred to, individually, as a "Group" and, in combination, as the "Groups," perform nearly all of the cardiac catheterization services at the Hospital.[2] Occasionally a case is completed by another group or by solo practitioners.

The Program Administrator. The Hospital has engaged [name redacted] (the "Program Administrator") to administer the Arrangement. The Program Administrator has collected data and analyzed and manages the Arrangement.[3] The Hospital has paid the Program Administrator a monthly fixed fee certified by the Requestors to be fair market value in an arm's-length transaction for services to be provided by the Program Administrator under the Arrangement. The fee has not been tied in any way to cost savings or the Groups' compensation under the Arrangement.

B. The Arrangement

Under the Arrangement, the Hospital has agreed to pay each Group a share of cost savings directly attributable to specific changes in that particular Group's cardiac catheterization

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[2]The Groups have members who also practice at other hospitals in the region; however, the Hospital is the primary practice location for most of the physicians in the Groups.

[3] The Program Administrator has developed a software product that measures cost, quality, and utilization on a national basis. The product is certified by the American College of Cardiology.

practices over two years. The Requestors implemented the Arrangement – and the Groups began performance of the specific changes in cardiac catheterization practices – prior to requesting this advisory opinion. The Hospital has not paid amounts owed to the Groups under the Arrangement, however, pending the outcome of this opinion.[4] Thus, we are treating the Arrangement as an existing arrangement for purposes of this advisory opinion. The Requestors have certified that the Hospital will make payments owed under the Arrangement upon receipt of a favorable advisory opinion. The Groups are the only physician practices participating in the Arrangement.

To develop the Arrangement, the Program Administrator conducted a study of the historical practices of the Groups with respect to cardiac catheterization procedures performed at the Hospital and identified twenty-three specific cost savings opportunities. The Program Administrator summarized the results of its study and the specific cost savings opportunities in a document entitled, "EXECUTIVE SUMMARY [NAME REDACTED] VALUESHARE FOR CARDIOLOGY" (the "Executive Summary").[5] The Hospital and the Groups reviewed the Executive Summary for medical appropriateness and each adopted its recommendations and conclusions.

In general, the Executive Summary recommended that the Groups change current cardiac catheterization practices to standardize their use of medical devices and supplies and to curb the inappropriate use or waste of medical devices and supplies. The Executive Summary identified twenty-seven specific recommendations that can be grouped roughly into the following three categories.[6]

- *Product Standardization.* For the first category, involving twenty-two recommendations, the Executive Summary recommended that the Groups standardize the types of cardiac catheterization devices and supplies (stents, balloons, interventional guidewires and catheters, vascular closure devices, diagnostic devices,

[4]Nonpayment of amounts owed pursuant to a contractual agreement does not, by itself, absolve parties from liability under the fraud and abuse laws.

[5]The Executive Summary is attached to this advisory opinion as Appendix A.

[6]While the Executive Summary contains twenty-three specific cost-savings opportunities, some of those opportunities include more than one recommendation and can therefore be classified in more than one category. Thus, the total number of recommendations exceeds the total number of cost-savings opportunities identified in the Executive Summary.

pacemakers, defibrillators and contrast agents) they employ.[7] The Groups were required to work in conjunction with the Hospital to evaluate and clinically review vendors and products. The Requestors have certified that they selected the preferred products eligible for payments under the Arrangement based on a process that first considered whether the products were clinically safe and effective. An assessment was then made whether the proposed standardization measures were appropriate on the basis of clinical criteria. Only thereafter did the Requestors consider cost. To the extent costs were a consideration, final selections of vendors and products were made on the basis of prices available to the Hospital for those particular products.

- *"Use as needed" Devices.* The second category, consisting of three recommendations, involved limiting the use of certain vascular closure devices and cutting balloons to an "as needed" basis (hereinafter, the "use as needed" recommendations) for coronary interventional and diagnostic procedures. The Requestors further certified that the specific vascular closure devices and cutting balloons remained readily available in the procedure room.

- *Product Substitutions.* The third category involved two recommendations to substitute, as appropriate, less costly contrast agents and anti-thrombotic medications for other products being used by the physicians (hereafter, the "product substitutions"). These recommendations may have an appreciable clinical significance. The Requestors certified that neither of the identified product substitutions adversely impacted patient care.[8]

The Arrangement contained several safeguards intended to protect against inappropriate reductions in services. Importantly, with respect to the product standardization, use as needed recommendations, and product substitution, the Requestors certified that the individual physicians made a patient-by-patient determination of the most appropriate device or supply and the availability of the full range of devices and supplies was not compromised by the product standardization, use as needed recommendations, or product substitution. The Requestors have further certified that individual physicians still had available the same selection of devices and supplies after implementation of the Arrangement as before, and that the economies gained through the Arrangement resulted

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[7]We note that the Executive Summary identified with specificity the vendors and products at issue.

[8]The Executive Summary identified with specificity the product substitutions.

from inherent clinical and fiscal value and not from restricting the availability of devices and supplies.

With respect to the use as needed recommendations and the product substitutions, the Arrangement utilized objective historical and clinical measures reasonably related to the practices and the patient population at the Hospital, and in some cases, national averages to establish "floors" beyond which no savings accrued to any Group. For example, according to the Requestors, diagnostic vascular closure devices had previously been utilized at the Hospital on 88% of the cases specified under the Arrangement. The Program Administrator determined through analysis of national data that it would be reasonable to reduce the use of diagnostic vascular closure devices on these cases to 37% of coronary patients and that this reduction would not adversely impact patient care. Thus, the Groups receive no share of any savings resulting from the reduction of use of diagnostic vascular closure devices beyond the 37% floor.

With regard to the product substitution of contrast agents, the Program Administrator identified national averages and historical patterns of use at the Hospital or at hospitals with comparable practices and patient populations and established quality thresholds beyond which no cost savings will be credited. The Executive Summary indicated that certain less expensive contrast agents could be used in 68% of the cases without an adverse impact on patient care. Accordingly, any savings from using a less expensive contrast agent in more than 68% of the cases will not be credited to the Groups.

For the product substitution of anti-thrombotic medications, no "floors" were set because substituting usage of the medications comported with national guidelines and other quality indicators. However, to ensure that this recommendation did not adversely affect the quality of care at the Hospital, the Program Administrator tracked the Hospital's performance of the covered cardiac catheterization procedures against the quality indicators established by the American College of Cardiology ("ACC") throughout the base years and contract years. (See infra definitions notes 9 and 10.) According to the Requestors, the ACC quality indicators, against which all of the Arrangement's recommendations were evaluated, reflect objective hospital baselines. The indicators are action-specific and not simply based on isolated patient outcome data unrelated to specific changes in cardiac catheterization practices. The ACC indicators incorporate enough specificity to permit correlation of outcomes with cardiac catheterization practices. No cost sharing amounts are allocated to the Groups for procedures involving reductions in historical ACC quality indicators.

According to the Program Administrator, to the extent implemented in accordance with the Executive Summary's specifications, the twenty-seven recommendations presented

substantial cost savings opportunities for the Hospital without any adverse impact on the quality of patient care.

Under the Arrangement, the Hospital intends to pay each of the Groups separately for 50% of the yearly savings achieved by the particular group when implementing the applicable recommendations in the Executive Summary. At the end of each year of the two-year Arrangement, cost savings were calculated separately for each Group for each of the applicable recommendations; this precluded shifting of cost savings and ensured that savings generated by utilization beyond the set targets, as applicable, were not credited to the Groups.

The sum of the two annual payments to each Group, when made, will constitute the entire compensation paid to the particular Group for services performed under the contract memorializing the Arrangement between that Group and the Hospital. The payment to each Group will be calculated using the same formula. For purposes of calculating the payment to each Group, the actual costs incurred for the items specified in the applicable recommendations when used by physicians of the particular Group during the specified procedures (the "current year costs"[9]) are subtracted from the historical costs for the same items when used during comparable procedures in the respective base year (the "base year costs"[10]). The Requestors rebased the Arrangement at the end of the first year so that the Groups will not receive duplicate payments for savings achieved in the first year. Specifically, at the end of the first year, Requestors calculated the amounts owed to the Groups as described above. The Requestors then reset the base year so that the first year of the Arrangement became the base year for the second year of the Arrangement. This annual rebasing method removed earlier accomplished savings from the accounting.

The current year costs for each of the two years were adjusted to account for any inappropriate reductions in use of items beyond the targets set in the Executive Summary. After receipt of a favorable advisory opinion, year-end payments will be made to the

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[9]The term "current year costs" used here represents the actual costs incurred during each of the two twelve-month periods that comprise the Arrangement. Current year costs were calculated for year one of the Arrangement and recalculated at the start of year two.

[10]Figures for two successive "base years" were calculated from historical costs during the twelve months immediately preceding the contracts' year one, and year two, respectively. For purposes of this opinion, the Arrangement is limited to the two year term of the contracts; accordingly, this opinion is without force and effect with respect to any future renewal or extension of the Arrangement. Notwithstanding, we note that any renewal or extension of the Arrangement should incorporate updated current year and base year costs.

Groups for 50% of the difference between their respective adjusted current year costs and base year costs for the first and second years, if any. Under the Arrangement, the Hospital is obligated to make these aggregate payments to each Group, each of which distributes profits among members on a per capita basis.

Calculation of payments to the Groups is subject to the following limitations:

- If a physician's volume of procedures payable by a Federal health care program in the current year exceeded the volume of like procedures payable by a Federal health care program performed in the base year which preceded it, there is no sharing of cost savings for the additional procedures.

- To minimize the physicians' financial incentive to steer more costly patients to other hospitals, the case severity, ages, and payors of the patient population treated under the Arrangement were monitored by a committee composed of representatives of the Requestors, using generally-accepted standards. If significant changes from historical measures indicated that a physician had altered his or her referral patterns in a manner beneficial to the Hospital as a result of the Arrangement, the physician at issue would have been terminated from participation in the Arrangement. No physicians were terminated.

- The Executive Summary identified projected cost savings, and the aggregate of payments paid to each Group, when made, will not exceed 50% of the Group's share of the projected cost savings identified in the initial base year. Each Group will be compensated solely for its own savings under the Arrangement.

The Hospital and the Groups documented the activities and the payment methodology under the Arrangement and will make the documentation available to the Secretary of the United States Department of Health and Human Services, upon request. In addition, the Hospital and the Groups disclosed the Arrangement to the patients, including the fact that the Groups' compensation was based on a percentage of the Hospital's cost savings. The disclosure was made to the patient before the patient was admitted to the Hospital for a procedure covered by the Arrangement; if pre-admission disclosure was impracticable (e.g., the patient was admitted for an unscheduled procedure or the need for the procedure was determined after admission), the disclosure was made before the patient consented to the procedure. The disclosures were in writing, and each patient had an opportunity, if they desired, to review details of the Arrangement, including the specific cost savings measures applicable to the patient's procedure.

II. LEGAL ANALYSIS

Programs like the Arrangement are designed to align incentives by offering physicians a portion of a hospital's cost savings in exchange for implementing cost saving strategies. Under the current reimbursement system, the burden of these costs falls on hospitals, not physicians. Payments to physicians based on cost savings may be intended to motivate them to reduce hospital costs associated with procedures performed by physicians at the hospitals.

Properly structured, arrangements that share cost savings can serve legitimate business and medical purposes. Specifically, properly structured arrangements may increase efficiency and reduce waste, thereby potentially increasing a hospital's profitability. However, such arrangements can potentially influence physician judgment to the detriment of patient care. Our concerns include, but are not limited to, the following: (i) stinting on patient care; (ii) "cherry picking" healthy patients and steering sicker (and more costly) patients to hospitals that do not offer such arrangements; (iii) payments in exchange for patient referrals; and (iv) unfair competition (a "race to the bottom") among hospitals offering cost savings programs to foster physician loyalty and to attract more referrals.

Hospital cost savings programs in general, and the Arrangement in particular, may implicate at least three Federal legal authorities: (i) the civil monetary penalty for reductions or limitations of direct patient care services provided to Federal health care program beneficiaries, sections 1128A(b)(1)-(2) of the Act; (ii) the anti-kickback statute, section 1128B(b) of the Act; and (iii) the physician self-referral law, section 1877 of the Act.[11] We address the first two of these authorities; section 1877 of the Act falls outside the scope of the OIG's advisory opinion authority. We express no opinion on the application of section 1877 of the Act to the Arrangement.

A. The Civil Monetary Penalty, Sections 1128A(b)(1)-(2) of the Act

Sections 1128A(b)(1)-(2) of the Act establish a civil monetary penalty ("CMP") against any hospital or critical access hospital that knowingly makes a payment directly or indirectly to a physician (and any physician that receives such a payment) as an inducement to reduce or limit items or services to Medicare or Medicaid beneficiaries under the physician's direct

[11] In addition, nonprofit hospital arrangements raise issues of private inurement and private benefit under the Internal Revenue Service's income tax regulations in connection with section 501(c)(3) of the Internal Revenue Code. See Rev. Rul. 69-383, 1969-2 C.B. 113. We express no opinion on the application of the Internal Revenue Code to the Arrangement.

care. Hospitals that make (and physicians that receive) such payments are liable for CMPs of up to $2,000 per patient covered by the payments. See id. There is no requirement that the prohibited payment be tied to a specific patient or to a reduction in medically necessary care. The CMP applies only to reductions or limitations of items or services provided to Medicare and Medicaid fee-for-service beneficiaries.[12]

The CMP prohibits payments by hospitals to physicians that may induce physicians to reduce or limit items or services furnished to their Medicare and Medicaid patients. A threshold inquiry is whether the Arrangement induces physicians to reduce or limit items or services. Given the specificity of the Arrangement, it is possible to review the opportunities for savings individually and evaluate their impact on patient care.

Having reviewed the twenty-seven recommendations, we conclude that all of the recommendations implicated the CMP. Simply put, with respect to the recommendations under the Arrangement regarding standardization of devices and supplies, limiting use of specific vascular closure devices and cutting balloons, and substitution of contrast agent and anti-thrombotic medication, the Arrangement might induce physicians to reduce or limit the then-current medical practice at the Hospital. We recognize that the then-current medical practice may have involved care that exceeded the requirements of medical necessity. However, whether the current medical practice reflects necessity or prudence is irrelevant for purposes of the CMP.

In sum, we find that the CMP applies to the recommendations for the product standardization, limiting use of devices and supplies, and product substitution. Notwithstanding, the Arrangement has several features that, in combination, provide sufficient safeguards so that we would not seek sanctions against the Requestors under sections 1128A(b)(1)-(2) of the Act.

First, the specific cost saving actions and resulting savings were clearly and separately identified. The transparency of the Arrangement allowed, and continues to allow, for public

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[12]Physician incentive arrangements related to Medicare risk-based managed care contracts, similar Medicaid contracts, and Medicare Advantage plans (formerly Medicare + Choice) are subject to regulation by the Secretary pursuant to sections 1876(i)(8), 1903(m)(2)(A)(x), and 1852(j)(4) of the Act (respectively), in lieu of being subject to sections 1128A(b)(1)-(2). See OIG letter regarding hospital-physician incentive plans for Medicare and Medicaid beneficiaries enrolled in managed care plans (dated August 19, 1999), available at http://oig.hhs.gov/fraud/docs/alertsandbulletins/gsletter.htm. See also 42 C.F.R. § 417.479 (Medicare HMOs or competitive medical plans); 42 C.F.R. § 422.208 (Medicare Advantage plans); 42 C.F.R. § 438.6 (Medicaid risk plans).

scrutiny and individual physician accountability for any adverse effects of the Arrangement, including any difference in treatment among patients based on nonclinical indicators. The transparency of the incentives for specific actions and specific procedures also facilitates accountability through the medical-legal professional liability system.

Second, the Requestors have proffered credible medical support for the position that implementation of the recommendations did not adversely affect patient care. The Arrangement was periodically reviewed by the Requestors to confirm that the Arrangement was not having an adverse impact on clinical care.[13]

Third, the amounts to be paid under the Arrangement have been calculated based on all procedures performed, regardless of the patients' insurance coverage, subject to the cap on payment for Federal health care program procedures. Moreover, the procedures to which the Arrangement applied were not disproportionately performed on Federal health care program beneficiaries. Additionally, the cost savings have been calculated on the Hospital's actual out-of-pocket acquisition costs, not an accounting convention.

Fourth, the Arrangement protected against inappropriate reductions in services by utilizing objective historical and clinical measures to establish baseline thresholds beyond which no savings accrued to the Groups. The Requestors have certified that these baseline measures were reasonably related to the Hospital's or comparable hospitals' practices and patient populations. These safeguards were action-specific and not simply based on isolated patient outcome data unrelated to the specific changes in cardiac catheterization practices.

Fifth, the product standardization portion of the Arrangement further protected against inappropriate reductions in services by ensuring that individual physicians still had available the same selection of devices and supplies after implementation of the Arrangement as before. The Arrangement was designed to produce savings through inherent clinical and fiscal value and not from restricting the availability of devices and supplies. As described above, clinical criteria guided the Requestors' process for selecting products to be standardized, and, to the extent cost considerations influenced selections

[13]We have had the Arrangement reviewed by an independent medical expert. The medical expert concluded that the cost savings measures, as described in the advisory opinion request and supplemental submissions, should not have adversely affected patient care. For purposes of this opinion, however, we rely solely on the Requestors' certifications and nothing in this advisory opinion should be construed as an endorsement or conclusion as to the medical propriety of the specific activities being undertaken as part of the Arrangement.

from among products determined to be clinically safe and effective, the cost considerations were limited to prices available to the Hospital for the particular products.

Sixth, the Hospital and the Groups provided written disclosures of their involvement in the Arrangement to patients whose care might have been affected by the Arrangement and provided patients an opportunity to review the cost savings recommendations prior to admission to the Hospital (or, where pre-admission consent was impracticable, prior to consenting to the procedure). While we do not believe that, standing alone, such disclosures offer sufficient protection from program or patient abuse, effective and meaningful disclosure offers some protection against possible abuses of patient trust.[14]

Seventh, the financial incentives under the Arrangement were reasonably limited in duration and amount.

Eighth, because each of the Groups distributes profits to its members on a per capita basis, any incentive for an individual physician to generate disproportionate cost savings was mitigated.

Our decision not to impose sanctions on the Requestors in connection with the Arrangement is an exercise of our discretion and is consistent with our Special Advisory Bulletin on "Gainsharing Arrangements and CMPs for Hospital Payments to Physicians to Reduce or Limit Services to Beneficiaries" (July 1999) (the "Special Advisory Bulletin"). We iterate that the CMP applies to any payment by a hospital to a physician that is intended to induce the reduction or limitation of items or services to Medicare or Medicaid patients under the physician's direct clinical care. The Arrangement is markedly different from "gainsharing" plans that purport to pay physicians a percentage of generalized cost savings not tied to specific, identifiable cost-lowering activities. Importantly, the Arrangement set out the specific actions to be taken and tied the remuneration to the actual, verifiable cost savings attributable to those actions. This transparency allowed an assessment of the likely effect of the Arrangement on quality of care and ensures that the identified actions are the cause of any savings.

"Gainsharing" plans can present substantial risks for both patient and program abuse – risks that were not present in the Arrangement. Given the limited duration and scope of the Arrangement, the safeguards provided sufficient protections against patient and program

[14]Ordinarily, we would expect patient disclosures to be coupled with patient satisfaction surveys that closely monitor patient perceptions of their care. However, in the context of the Arrangement, which focuses on items used in cardiac catheterization procedures, we believe that patient satisfaction surveys would not be effective.

abuse. Other arrangements, including those that are longer in duration or more expansive in scope than the Arrangement, are likely to require additional or different safeguards.

B. The Anti-Kickback Statute

The anti-kickback statute makes it a criminal offense knowingly and willfully to offer, pay, solicit, or receive any remuneration to induce or reward referrals of items or services reimbursable by a Federal health care program. See section 1128B(b) of the Act. Where remuneration is paid purposefully to induce or reward referrals of items or services payable by a Federal health care program, the anti-kickback statute is violated. By its terms, the statute ascribes criminal liability to parties on both sides of an impermissible "kickback" transaction. For purposes of the anti-kickback statute, "remuneration" includes the transfer of anything of value, directly or indirectly, overtly or covertly, in cash or in kind.

The statute has been interpreted to cover any arrangement where one purpose of the remuneration was to obtain money for the referral of services or to induce further referrals. United States v. Kats, 871 F.2d 105 (9th Cir. 1989); United States v. Greber, 760 F.2d 68 (3d Cir.), cert. denied, 474 U.S. 988 (1985). Violation of the statute constitutes a felony punishable by a maximum fine of $25,000, imprisonment up to five years, or both. Conviction will also lead to automatic exclusion from Federal health care programs, including Medicare and Medicaid. Where a party commits an act described in section 1128B(b) of the Act, the OIG may initiate administrative proceedings to impose civil monetary penalties on such party under section 1128A(a)(7) of the Act. The OIG may also initiate administrative proceedings to exclude such party from the Federal health care programs under section 1128(b)(7) of the Act.

The Department of Health and Human Services has promulgated safe harbor regulations that define practices that are not subject to the anti-kickback statute because such practices would be unlikely to result in fraud or abuse. See 42 C.F.R. § 1001.952. The safe harbors set forth specific conditions that, if met, assure entities involved of not being prosecuted or sanctioned for the arrangement qualifying for the safe harbor. However, safe harbor protection is afforded only to those arrangements that precisely meet all of the conditions set forth in the safe harbor.

The safe harbor for personal services and management contracts, 42 C.F.R. § 1001.952(d), is potentially applicable to the Arrangement. In relevant part for purposes of this advisory opinion, the personal services safe harbor requires that the aggregate compensation paid for the services be set in advance and consistent with fair market value in arm's-length transactions. The Arrangement cannot fit in the safe harbor because the payment owed to the Groups was calculated on a percentage basis, and thus the aggregate compensation was

not set in advance. However, the absence of safe harbor protection is not fatal. Instead, the Arrangement must be subject to case-by-case evaluation.

Like any compensation arrangement between a hospital and a physician who admits or refers patients to such hospital, we are concerned that the Arrangement could be used to disguise remuneration from the Hospital to reward or induce referrals by the Groups. Specifically, the Arrangement could encourage the physicians to admit Federal health care program patients to the Hospital, since the physicians receive not only their Medicare Part B professional fee, but also, indirectly, a share of the Hospital's payment, depending on cost savings. In other words, the more procedures a physician performs at the Hospital, the more money he or she is likely to receive under the Arrangement.

Multiple-year gainsharing arrangements raise a particular concern, in that they can inappropriately carry over earlier-accomplished savings across years, effectively accounting for them more than once. The resulting unearned duplicate payments can amount to unlawful kickbacks from hospitals to physicians, if accompanied by illicit intent. The annual rebasing method adopted by the Requestors removes earlier accomplished savings from the accounting and thereby avoids improper duplication of physician payments, reducing the accompanying risk of kickbacks.

While we believe the Arrangement could result in illegal remuneration if the requisite intent to induce referrals were present, we will not impose sanctions in the particular circumstances presented here and as qualified below.

First, the circumstances and safeguards of the Arrangement reduced the likelihood that the Arrangement has been used to attract referring physicians or to increase referrals from existing physicians. Specifically, participation in the Arrangement was limited to physicians already on the medical staff, thus limiting the likelihood that the Arrangement would attract other physicians. In addition, the potential savings derived from procedures for Federal health care program beneficiaries were capped based on the physicians' prior year's admissions of Federal health care program beneficiaries. The period for which payments have been calculated was limited to one year (and the Arrangement was rebased at the end of the first year), and the overall amount of available cost savings payments over the entire two year term of the contract has been capped, reducing any incentive to switch facilities. Finally, admissions were monitored for changes in severity, age, or payor. Thus, while the incentive to refer was not necessarily eliminated, it has been substantially reduced.

Second, the structure of the Arrangement eliminated the risk that the Arrangement has been used to reward surgeons or other physicians who refer patients to the Groups or their physicians. The Groups were the sole participants in the Arrangement and were composed

entirely of cardiologists and interventional radiologists; no surgeons or other physicians are members of the Groups or will share in their profit distributions. Within the Groups, profits are distributed to members on a per capita basis, mitigating any incentive for an individual physician to generate disproportionate cost savings.

Third, the Arrangement set out with specificity the particular actions that generated the cost savings on which the payments will be based. The recommendations in the Executive Summary represented a change in cardiac catheterization practice, for which the physicians were responsible and had liability exposure. The product standardization, limitation on use of devices and supplies, and product substitution each carried some increased liability risk for the physicians. It is not unreasonable for the physicians to receive compensation for the increased risk from the change in practice. Moreover, the payments to be made represent portions of two years' worth of cost savings and are limited in amount (i.e., the rebasing and aggregate cap), duration (i.e., the limited contract term), and scope (i.e., the total savings that can be achieved from the implementation of any one recommendation are limited by appropriate utilization levels). The payments under the Arrangement do not appear unreasonable, given, among other things, the nature of the actions required of the physicians to have implemented the twenty-seven recommended actions, the specificity of the payment formula, and the cap on total remuneration to the Groups.[15] We caution that payments of 50% in other arrangements, including multi-year arrangements or arrangements with generalized cost savings formulae, could well lead to a different result.

In light of these circumstances and safeguards, the Arrangement poses a low risk of fraud or abuse under the anti-kickback statute.

III. CONCLUSION

Notwithstanding the foregoing, we iterate our concerns regarding many arrangements between hospitals and physicians to share cost savings. Improperly designed or implemented arrangements risk adversely affecting patient care and could be vehicles to disguise payments for referrals. For example, an arrangement that cannot be adequately and accurately measured for quality of care would pose a high risk of fraud or abuse, as would one that rewards physicians based on overall cost savings without accountability for specific cost reduction measures. Moreover, arrangements structured so as to pose a heightened

[15]We are precluded by statute from opining on whether fair market value shall be or was paid for goods, services, or property. See 42 U.S.C. § 1320a-7d(b)(3)(A). While the Requestors have certified that the payments under the Arrangement are consistent with fair market value, we do not rely on that certification in this opinion, nor have we have made an independent fair market value assessment.

potential for patient steering and unfair competition would be considered suspect. In short, this opinion is predicated on the specific arrangement posed by the Requestors and is limited to that specific arrangement. Other apparently similar arrangements could raise different concerns and lead to a different result.

Based on the information provided and the totality of the facts as described and certified in your request for an advisory opinion and supplemental submissions, we conclude that: (i) the Arrangement could constitute an improper payment to induce reduction or limitation of services pursuant to sections 1128A(b)(1)-(2) of the Act, but that the OIG would not impose sanctions on the Requestors in connection with the Arrangement; and (ii) the Arrangement could potentially generate prohibited remuneration under the anti-kickback statute, if the requisite intent to induce or reward referrals of Federal health care program business were present, but that the OIG would not impose administrative sanctions on the Requestors under sections 1128(b)(7) or 1128A(a)(7) of the Act (as those sections relate to the commission of acts described in section 1128B(b) of the Act) in connection with the Arrangement.

IV. LIMITATIONS

The limitations applicable to this opinion include the following:

- This advisory opinion is issued only to [names redacted], the requestors of this opinion. This advisory opinion has no application to, and cannot be relied upon by, any other individual or entity.

- This advisory opinion may not be introduced into evidence in any matter involving an entity or individual that is not a requestor to this opinion.

- This advisory opinion is applicable only to the statutory provisions specifically noted above. No opinion is expressed or implied herein with respect to the application of any other Federal, state, or local statute, rule, regulation, ordinance, or other law that may be applicable to the Arrangement, including, without limitation, the physician self-referral law, section 1877 of the Act.

- This advisory opinion will not bind or obligate any agency other than the U.S. Department of Health and Human Services.

- This advisory opinion is limited in scope to the specific arrangement described in this letter and has no applicability to other arrangements, even those that appear similar in nature or scope.

- No opinion is expressed herein regarding the liability of any party under the False Claims Act or other legal authorities for any improper billing, claims submission, cost reporting, or related conduct.

- This opinion is also subject to any additional limitations set forth at 42 C.F.R. Part 1008.

The OIG will not proceed against [names redacted] with respect to any action that is part of the Arrangement taken in good faith reliance upon this advisory opinion, as long as all of the material facts have been fully, completely, and accurately presented, and the Arrangement in practice comports with the information provided. The OIG reserves the right to reconsider the questions and issues raised in this advisory opinion and, where the public interest requires, rescind, modify, or terminate this opinion. In the event that this advisory opinion is modified or terminated, the OIG will not proceed against [names redacted] with respect to any action taken in good faith reliance upon this advisory opinion, where all of the relevant facts were fully, completely, and accurately presented, and where such action was promptly discontinued upon notification of the modification or termination of this advisory opinion. An advisory opinion may be rescinded only if the relevant and material facts have not been fully, completely, and accurately disclosed to the OIG.

Sincerely,

/Lewis Morris/

Lewis Morris
Chief Counsel to the Inspector General

[Appendix A and Distribution List redacted]

[*We redact certain identifying information and certain potentially privileged, confidential, or proprietary information associated with the individual or entity, unless otherwise approved by the requestor.*]

Issued: June 23, 2009

Posted: June 30, 2009

To: Attached Distribution List

Re: OIG Advisory Opinion No. 09-06

Ladies and Gentlemen:

We are writing in response to your request for an advisory opinion concerning an existing arrangement in which a hospital has agreed to share with a cardiology group, a vascular surgical group, and an interventional radiology group a percentage of the hospital's cost savings arising from the physicians' implementation of a number of cost-reduction measures in certain cardiac catheterization procedures[1] (the "Arrangement"). The cost savings are measured based on the physicians' use of specific medical devices and supplies during designated cardiac catheterization procedures. You have inquired whether the Arrangement constitutes grounds for sanctions arising under: (i) the civil monetary penalty for a hospital's payment to a physician to induce the reduction or limitation of services to Medicare or Medicaid beneficiaries under the physician's direct care, sections 1128A(b)(1)-(2) of the Social Security Act (the "Act"); or (ii) the exclusion authority at section 1128(b)(7) of the Act or the civil monetary penalty provision at section 1128A(a)(7) of the Act, as those sections relate to the commission of acts described in section 1128B(b) of the Act, the anti-kickback statute.

[1] The request refers to cardiac catheterization laboratory and special procedures laboratory procedures, services, and practices. For purposes of this opinion, we will refer to these collectively as "cardiac catheterization procedures."

You have certified that all of the information provided in your request, including all supplemental submissions, is true and correct and constitutes a complete description of the relevant facts and agreements among the parties.

In issuing this opinion, we have relied solely on the facts and information presented to us. We have not undertaken an independent investigation of such information. This opinion is limited to the facts presented. If material facts have not been disclosed or have been misrepresented, this opinion is without force and effect.

Based on the facts certified in your request for an advisory opinion and supplemental submissions, we conclude that: (i) the Arrangement could constitute an improper payment to induce the reduction or limitation of services pursuant to sections 1128A(b)(1)-(2) of the Act, but that the Office of Inspector General ("OIG") would not impose sanctions on [names redacted] (collectively, the "Requestors"), in connection with the Arrangement; and (ii) the Arrangement could potentially generate prohibited remuneration under the anti-kickback statute, if the requisite intent to induce or reward referrals of Federal health care program business were present, but that the OIG would not impose administrative sanctions on the Requestors under sections 1128(b)(7) or 1128A(a)(7) of the Act (as those sections relate to the commission of acts described in section 1128B(b) of the Act) in connection with the Arrangement. This opinion is limited to the Arrangement and, therefore, we express no opinion about any ancillary agreements or arrangements disclosed or referenced in your request for an advisory opinion or supplemental submissions.

This opinion may not be relied on by any persons other than the Requestors and is further qualified as set out in Part IV below and in 42 C.F.R. Part 1008.

I. FACTUAL BACKGROUND

A. Parties

The Hospital. At all times relevant to this advisory opinion, [name redacted] (the "Hospital") was an acute care hospital in [city and state names redacted] that offered a broad range of inpatient and outpatient hospital services, including cardiac catheterization procedures, and was a participating provider in the Medicare and Medicaid programs.[2]

The Cardiology Group. [Name redacted] (the "Cardiology Group") is a professional corporation that employs exclusively cardiologists who are duly licensed in the State of [state name redacted] and have active medical staff privileges at the Hospital. At all times relevant to this advisory opinion, the Cardiology Group referred patients to the Hospital for

[2] After the contract year (see infra definition note 8), there was a restructuring and the Hospital became an outpatient facility.

inpatient and outpatient hospital services. The Cardiology Group entered into a contract with the Hospital that set forth the projected savings opportunities available to it.

The Interventional Radiology Group. [Name redacted] (the "Interventional Radiology Group") is a professional corporation that employs exclusively interventional radiologists who are duly licensed in the State of [state name redacted] and have active medical staff privileges at the Hospital. At all times relevant to this advisory opinion, the Interventional Radiology Group referred patients to the Hospital for inpatient and outpatient hospital services. The Interventional Radiology Group entered into a contract with the Hospital that set forth the projected savings opportunities available to it.

The Vascular Surgical Group. [Name redacted] (the "Vascular Surgical Group") is a professional corporation that employs exclusively vascular surgeons who are duly licensed in the State of [state name redacted] and have active medical staff privileges at the Hospital. At all times relevant to this advisory opinion, the Vascular Surgical Group referred patients to the Hospital for inpatient and outpatient hospital services. The Vascular Surgical Group entered into a contract with the Hospital that set forth the projected savings opportunities available to it.

In combination, the Cardiology Group, the Interventional Radiology Group, and the Vascular Surgical Group, herein referred to, individually, as a "Group" and, collectively, as the "Groups," perform nearly all of the cardiac catheterization procedures at the Hospital.[3] Occasionally a procedure is performed by another group or by solo practitioners.

The Program Administrator. The Hospital has engaged [name redacted] (the "Program Administrator") to administer the Arrangement. The Program Administrator has collected data and analyzed and manages the Arrangement.[4] The Hospital paid the Program Administrator a monthly fixed fee certified by the Requestors to be fair market value in an arm's-length transaction for services to be provided by the Program Administrator under the Arrangement. The fee was not tied in any way to cost savings or the Groups' compensation under the Arrangement.

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[3] The Groups have members who also practice at other hospitals in the region; however, at all times relevant to this advisory opinion, the Hospital was the primary practice location for most of the physicians in the Groups.

[4] The Program Administrator has developed a software product that measures cost, quality, and utilization on a national basis. The product is certified by the American College of Cardiology ("ACC").

B. The Arrangement

Under the Arrangement, the Hospital has agreed to pay each Group a share of the cost savings directly attributable to specific changes in that particular Group's cardiac catheterization procedures. The Requestors implemented the Arrangement—and the Groups began performance of the specific changes in cardiac catheterization procedures—prior to requesting this advisory opinion. The Hospital has not paid amounts owed to the Groups under the Arrangement, however, pending the outcome of this opinion.[5] Thus, we are treating the Arrangement as an existing arrangement for purposes of this advisory opinion. The Requestors have certified that the Hospital will make payments owed under the Arrangement upon receipt of a favorable advisory opinion. The Groups are the only physician practices participating in the Arrangement.

To develop the Arrangement, the Program Administrator conducted a study of the historical practices of the Groups with respect to cardiac catheterization procedures performed at the Hospital and identified twenty-one specific cost-savings opportunities. The Program Administrator summarized the results of its study and the specific cost-savings opportunities in a document entitled, "EXECUTIVE SUMMARY [NAME REDACTED] VALUESHARE FOR CARDIOLOGY" (the "Executive Summary").[6] The Hospital and the Groups reviewed the Executive Summary for medical appropriateness and each adopted its recommendations and conclusions.

The Executive Summary identified twenty-one specific recommendations that can be grouped roughly into the category of product standardization. The Executive Summary recommended that the Groups change current cardiac catheterization procedures to standardize the types of cardiac catheterization devices and supplies (stents, balloons, interventional guidewires and catheters, vascular closure devices, diagnostic devices, pacemakers, and defibrillators) they employ.[7] The Groups were required to work in conjunction with the Hospital to evaluate and clinically review vendors and products. The Requestors have certified that they selected the preferred products eligible for payments under the Arrangement based on a process that first considered whether the products were clinically safe and effective. An assessment was then made whether the proposed standardization measures were appropriate on the basis of clinical criteria. Only thereafter

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[5] Nonpayment of amounts owed pursuant to a contractual agreement does not, by itself, absolve parties from liability under the fraud and abuse laws.

[6] The Executive Summary is attached to this advisory opinion as Appendix A.

[7] The Executive Summary identified with specificity the products at issue.

did the Requestors consider cost. To the extent costs were a consideration, final selections of vendors and products were made on the basis of prices available to the Hospital for those particular products.

The Arrangement contained several safeguards intended to protect against inappropriate reductions in services. Importantly, the Requestors certified that the individual physicians made a patient-by-patient determination of the most appropriate device or supply and the availability of the full range of devices and supplies was not compromised by the product standardization. The Requestors have further certified that individual physicians still had available the same selection of devices and supplies after implementation of the Arrangement as before, and that the economies gained through the Arrangement resulted from inherent clinical and fiscal value and not from restricting the availability of devices and supplies.

In addition, to ensure that the recommendations did not adversely affect the quality of care at the Hospital, the Program Administrator tracked the Hospital's performance of the covered cardiac catheterization procedures against the quality indicators established by the ACC throughout the base year and contract year. (See infra definitions notes 8 and 9.) According to the Requestors, the ACC quality indicators, against which all of the Arrangement's recommendations were evaluated, reflect objective hospital baselines. The indicators are action-specific and not simply based on isolated patient outcome data unrelated to specific changes in cardiac catheterization procedures. The ACC indicators incorporate enough specificity to permit correlation of outcomes with cardiac catheterization procedures. The Hospital will not allocate any cost-sharing amounts to the Groups if the cardiac catheterization procedures performed by the Groups involve reductions in the Hospital's quality as measured against the ACC quality indicators.

According to the Program Administrator, to the extent implemented in accordance with the Executive Summary's specifications, the twenty-one recommendations presented substantial cost-savings opportunities for the Hospital without any adverse impact on the quality of patient care.

Under the Arrangement, the Hospital intends to pay each of the Groups separately for 50% of the savings achieved by the particular Group when implementing the applicable recommendations in the Executive Summary. At the end of the applicable year (the "contract year" [8]), cost savings were calculated separately for each Group for each of the applicable recommendations; this precluded shifting of cost savings and ensured that

[8] The contract year was the twelve-month period for which the Groups will be compensated under the Arrangement.

savings generated by procedures involving reductions in historical ACC quality indicators were not credited to the Groups.

The payments to each Group, when made, will constitute the entire compensation paid to the particular Group for services performed under the contract memorializing the Arrangement between that Group and the Hospital. The payment to each Group will be calculated using the same formula. For purposes of calculating the payment to each Group, the actual costs incurred during the contract year for the items specified in the applicable recommendations when used by physicians of the particular Group during the specified procedures (the "contract year costs") are subtracted from the historical costs for the same items when used during comparable procedures in the base year[9] (the "base year costs"[10]).

After receipt of a favorable advisory opinion, payments will be made to the Groups for 50% of the difference between their respective contract year costs and base year costs, if any. Under the Arrangement, the Hospital is obligated to make aggregate payments to each Group, each of which distributes profits among members on a per capita basis.

Calculation of payments to the Groups is subject to the following limitations:

- If a physician's volume of procedures payable by a Federal health care program in the contract year exceeded the volume of like procedures payable by a Federal health care program performed in the base year, there is no sharing of cost savings for the additional procedures.

- To minimize the physicians' financial incentive to steer more costly patients to other hospitals, the case severity, ages, and payors of the patient population treated under the Arrangement were monitored by a committee composed of representatives of the Requestors, using generally-accepted standards. If significant changes from historical measures indicated that a physician had altered his or her referral patterns in a manner beneficial to the Hospital as a result of the Arrangement, the physician at issue would have been terminated from participation in the Arrangement. No physicians were terminated.

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[9] The base year was the twelve-month period immediately preceding the contract year.

[10] Figures for the base year costs were calculated from historical costs during the base year. For purposes of this opinion, the Arrangement is limited to the one-year term of the contracts; accordingly, this opinion is without force and effect with respect to any future renewal or extension of the Arrangement. Notwithstanding, we note that any renewal or extension of the Arrangement should incorporate updated base year costs.

- The Executive Summary identified projected cost savings, and the aggregate of payments paid to each Group, when made, will not exceed 50% of the Group's share of the projected cost savings identified in the base year. Each Group will be compensated solely for its own savings under the Arrangement.

The Hospital and the Groups documented the activities and the payment methodology under the Arrangement and will make the documentation available to the Secretary of the United States Department of Health and Human Services, upon request. In addition, the Hospital and the Groups disclosed the Arrangement to the patients, including the fact that the Groups' compensation was based on a percentage of the Hospital's cost savings. The disclosure was made to the patient before the patient was admitted to the Hospital for a procedure covered by the Arrangement; if pre-admission disclosure was impracticable (e.g., the patient was admitted for an unscheduled procedure or the need for the procedure was determined after admission), the disclosure was made before the patient consented to the procedure. The disclosures were in writing, and each patient had an opportunity, if they desired, to review details of the Arrangement, including the specific cost-savings measures applicable to the patient's procedure.

II. LEGAL ANALYSIS

Programs like the Arrangement are designed to align incentives by offering physicians a portion of a hospital's cost savings in exchange for implementing cost-saving strategies. Under the current reimbursement system, the burden of these costs falls on hospitals, not physicians. Payments to physicians based on cost savings may be intended to motivate them to reduce hospital costs associated with procedures performed by physicians at the hospitals.

Properly structured, arrangements that share cost savings can serve legitimate business and medical purposes. Specifically, properly structured arrangements may increase efficiency and reduce waste, thereby potentially increasing a hospital's profitability. However, such arrangements can potentially influence physician judgment to the detriment of patient care. Our concerns include, but are not limited to, the following: (i) stinting on patient care; (ii) "cherry picking" healthy patients and steering sicker (and more costly) patients to hospitals that do not offer such arrangements; (iii) payments in exchange for patient referrals; and (iv) unfair competition (a "race to the bottom") among hospitals offering cost-savings programs to foster physician loyalty and to attract more referrals.

Hospital cost-savings programs in general, and the Arrangement in particular, may implicate at least three Federal legal authorities: (i) the civil monetary penalty for reductions or limitations of direct patient care services provided to Federal health care

program beneficiaries, sections 1128A(b)(1)-(2) of the Act; (ii) the anti-kickback statute, section 1128B(b) of the Act; and (iii) the physician self-referral law, section 1877 of the Act.[11] We address the first two of these authorities; section 1877 of the Act falls outside the scope of the OIG's advisory opinion authority. We express no opinion on the application of section 1877 of the Act to the Arrangement.

A. The Civil Monetary Penalty, Sections 1128A(b)(1)-(2) of the Act

Sections 1128A(b)(1)-(2) of the Act ("CMP") establish a civil monetary penalty against any hospital or critical access hospital that knowingly makes a payment directly or indirectly to a physician (and any physician who receives such a payment) as an inducement to reduce or limit items or services to Medicare or Medicaid beneficiaries under the physician's direct care. Hospitals that make (and physicians who receive) such payments are liable for civil monetary penalties of up to $2,000 per patient covered by the payments. See id. There is no requirement that the prohibited payment be tied to a specific patient or to a reduction in medically necessary care. The CMP applies only to reductions or limitations of items or services provided to Medicare and Medicaid fee-for-service beneficiaries.[12]

The CMP prohibits payments by hospitals to physicians that may induce physicians to reduce or limit items or services furnished to their Medicare and Medicaid patients. A threshold inquiry is whether the Arrangement induces physicians to reduce or limit items or services. Given the specificity of the Arrangement, it is possible to review the opportunities for savings individually and evaluate their impact on patient care.

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[11] In addition, nonprofit hospital arrangements raise issues of private inurement and private benefit under the Internal Revenue Service's income tax regulations in connection with section 501(c)(3) of the Internal Revenue Code. See Rev. Rul. 69-383, 1969-2 C.B. 113. We express no opinion on the application of the Internal Revenue Code to the Arrangement.

[12] Physician incentive arrangements related to Medicare risk-based managed care contracts, similar Medicaid contracts, and Medicare Advantage plans (formerly Medicare + Choice) are subject to regulation by the Secretary pursuant to sections 1876(i)(8), 1903(m)(2)(A)(x), and 1852(j)(4) of the Act (respectively), in lieu of being subject to sections 1128A(b)(1)-(2). See OIG letter regarding hospital-physician incentive plans for Medicare and Medicaid beneficiaries enrolled in managed care plans (dated August 19, 1999), available at http://oig.hhs.gov/fraud/docs/alertsandbulletins/gsletter.htm. See also 42 C.F.R. § 417.479 (Medicare HMOs or competitive medical plans); 42 C.F.R. § 422.208 (Medicare Advantage plans); 42 C.F.R. § 438.6 (Medicaid risk plans).

Having reviewed the twenty-one recommendations, we conclude that all of the recommendations implicated the CMP. Simply put, with respect to the recommendations under the Arrangement regarding standardization of devices and supplies, the Arrangement might induce physicians to reduce or limit the then-current medical practice at the Hospital. We recognize that the then-current medical practice may have involved care that exceeded the requirements of medical necessity. However, whether the current medical practice reflects necessity or prudence is irrelevant for purposes of the CMP.

In sum, we find that the CMP applies to the recommendations for product standardization. Notwithstanding, the Arrangement has several features that, in combination, provide sufficient safeguards so that we would not seek sanctions against the Requestors under sections 1128A(b)(1)-(2) of the Act.

First, the specific cost-saving actions and resulting savings were clearly and separately identified. The transparency of the Arrangement allowed, and continues to allow, for public scrutiny and individual physician accountability for any adverse effects of the Arrangement, including any difference in treatment among patients based on nonclinical indicators. The transparency of the incentives for specific actions and specific procedures also facilitates accountability through the medical-legal professional liability system.

Second, the Requestors have proffered credible medical support for the position that implementation of the recommendations did not adversely affect patient care. The Arrangement was periodically reviewed by the Requestors to confirm that the Arrangement was not having an adverse impact on clinical care.[13]

Third, the amounts to be paid under the Arrangement have been calculated based on all procedures performed, regardless of the patients' insurance coverage, subject to the cap on payment for Federal health care program procedures. Moreover, the procedures to which the Arrangement applied were not disproportionately performed on Federal health care program beneficiaries. Additionally, the cost savings have been calculated on the Hospital's actual out-of-pocket acquisition costs, not an accounting convention.

[13] We have had the Arrangement reviewed by an independent medical expert. The medical expert concluded that the cost-savings measures, as described in the advisory opinion request and supplemental submissions, should not have adversely affected patient care. For purposes of this opinion, however, we rely solely on the Requestors' certifications, and nothing in this advisory opinion should be construed as an endorsement or conclusion as to the medical propriety of the specific activities being undertaken as part of the Arrangement.

Fourth, the Arrangement protected against inappropriate reductions in services by utilizing objective historical and clinical measures to establish baseline thresholds beyond which no savings accrued to the Groups. The Requestors have certified that these baseline measures were reasonably related to the Hospital's or comparable hospitals' practices and patient populations. These safeguards were action-specific and not simply based on isolated patient outcome data unrelated to the specific changes in cardiac catheterization procedures.

Fifth, the Arrangement further protected against inappropriate reductions in services by ensuring that individual physicians still had available the same selection of devices and supplies after implementation of the Arrangement as before. The Arrangement was designed to produce savings through inherent clinical and fiscal value and not from restricting the availability of devices and supplies. As described above, clinical criteria guided the Requestors' process for selecting products to be standardized, and, to the extent cost considerations influenced selections from among products determined to be clinically safe and effective, the cost considerations were limited to prices available to the Hospital for the particular products.

Sixth, the Hospital and the Groups provided written disclosures of their involvement in the Arrangement to patients whose care might have been affected by the Arrangement and provided patients an opportunity to review the cost-savings recommendations prior to admission to the Hospital (or, where pre-admission consent was impracticable, prior to consenting to the procedure). While we do not believe that, standing alone, such disclosures offer sufficient protection from program or patient abuse, effective and meaningful disclosure offers some protection against possible abuses of patient trust.[14]

Seventh, the financial incentives under the Arrangement were reasonably limited in duration and amount.

Eighth, because each of the Groups distributes profits to its members on a per capita basis, any incentive for an individual physician to generate disproportionate cost savings was mitigated.

Our decision not to impose sanctions on the Requestors in connection with the Arrangement is an exercise of our discretion and is consistent with our Special Advisory Bulletin on "Gainsharing Arrangements and CMPs for Hospital Payments to Physicians to Reduce or

[14] Ordinarily, we would expect patient disclosures to be coupled with patient satisfaction surveys that closely monitor patient perceptions of their care. However, in the context of the Arrangement, which focuses on items used in cardiac catheterization procedures, we believe that patient satisfaction surveys would not be effective.

Limit Services to Beneficiaries" (July 1999) (the "Special Advisory Bulletin"). We iterate that the CMP applies to any payment by a hospital to a physician that is intended to induce the reduction or limitation of items or services to Medicare or Medicaid patients under the physician's direct clinical care. The Arrangement is markedly different from "gainsharing" plans that purport to pay physicians a percentage of generalized cost savings not tied to specific, identifiable cost-lowering activities. Importantly, the Arrangement set out the specific actions to be taken and tied the remuneration to the actual, verifiable cost savings attributable to those actions. This transparency allowed an assessment of the likely effect of the Arrangement on quality of care and ensures that the identified actions are the cause of any savings.

"Gainsharing" plans can present substantial risks for both patient and program abuse—risks that are not present in the Arrangement. The limited duration and scope of the Arrangement, in combination with the other safeguards described above, provided sufficient protections against patient and program abuse. Other arrangements, including those that are longer in duration or more expansive in scope than the Arrangement, are likely to require additional or different safeguards.

B. The Anti-Kickback Statute

The anti-kickback statute makes it a criminal offense knowingly and willfully to offer, pay, solicit, or receive any remuneration to induce or reward referrals of items or services reimbursable by a Federal health care program. See section 1128B(b) of the Act. Where remuneration is paid purposefully to induce or reward referrals of items or services payable by a Federal health care program, the anti-kickback statute is violated. By its terms, the statute ascribes criminal liability to parties on both sides of an impermissible "kickback" transaction. For purposes of the anti-kickback statute, "remuneration" includes the transfer of anything of value, directly or indirectly, overtly or covertly, in cash or in kind.

The statute has been interpreted to cover any arrangement where one purpose of the remuneration was to obtain money for the referral of services or to induce further referrals. United States v. Kats, 871 F.2d 105 (9th Cir. 1989); United States v. Greber, 760 F.2d 68 (3d Cir.), cert. denied, 474 U.S. 988 (1985). Violation of the statute constitutes a felony punishable by a maximum fine of $25,000, imprisonment up to five years, or both. Conviction will also lead to automatic exclusion from Federal health care programs, including Medicare and Medicaid. Where a party commits an act described in section 1128B(b) of the Act, the OIG may initiate administrative proceedings to impose civil monetary penalties on such party under section 1128A(a)(7) of the Act. The OIG may also initiate administrative proceedings to exclude such party from the Federal health care programs under section 1128(b)(7) of the Act.

The Department of Health and Human Services has promulgated safe harbor regulations that define practices that are not subject to the anti-kickback statute because such practices would be unlikely to result in fraud or abuse. See 42 C.F.R. § 1001.952. The safe harbors set forth specific conditions that, if met, assure entities involved of not being prosecuted or sanctioned for the arrangement qualifying for the safe harbor. However, safe harbor protection is afforded only to those arrangements that precisely meet all of the conditions set forth in the safe harbor.

The safe harbor for personal services and management contracts, 42 C.F.R. § 1001.952(d), is potentially applicable to the Arrangement. In relevant part for purposes of this advisory opinion, the personal services safe harbor requires that the aggregate compensation paid for the services be set in advance and consistent with fair market value in arm's-length transactions. The Arrangement cannot fit in the safe harbor because the payment owed to the Groups was calculated on a percentage basis, and thus the aggregate compensation was not set in advance. However, the absence of safe harbor protection is not fatal. Instead, the Arrangement must be subject to case-by-case evaluation.

Like any compensation arrangement between a hospital and a physician who admits or refers patients to such hospital, we are concerned that the Arrangement could be used to disguise remuneration from the Hospital to reward or induce referrals by the Groups. Specifically, the Arrangement could encourage the physicians to admit Federal health care program patients to the Hospital, since the physicians receive not only their Medicare Part B professional fee, but also, indirectly, a share of the Hospital's payment, depending on cost savings. In other words, the more procedures a physician performs at the Hospital, the more money he or she is likely to receive under the Arrangement.

While we believe the Arrangement could result in illegal remuneration if the requisite intent to induce referrals were present, we will not impose sanctions in the particular circumstances presented here and as qualified below.

First, the circumstances and safeguards of the Arrangement reduced the likelihood that the Arrangement has been used to attract referring physicians or to increase referrals from existing physicians. Specifically, participation in the Arrangement was limited to physicians already on the medical staff, thus limiting the likelihood that the Arrangement would attract other physicians. In addition, the potential savings derived from procedures for Federal health care program beneficiaries were capped based on the physicians' prior year's admissions of Federal health care program beneficiaries. The period for which payments were calculated was limited to one year, and the overall amount of available cost-savings payments over the one-year term of the contracts was capped, reducing any incentive to switch facilities. Finally, admissions were monitored for changes in severity,

age, or payor. Thus, while the incentive to refer was not necessarily eliminated, it was substantially reduced.

Second, the structure of the Arrangement eliminated the risk that the Arrangement has been used to reward surgeons or other physicians who refer patients to the Groups or their physicians. The Groups were the sole participants in the Arrangement and each was composed entirely of physicians in a single specialty (i.e., cardiology, interventional radiology, and vascular surgery, respectively); no surgeons or other physicians are members of the Groups or will share in their profit distributions. Within the Groups, profits are distributed to members on a per capita basis, mitigating any incentive for an individual physician to generate disproportionate cost savings.

Third, the Arrangement set out with specificity the particular actions that generated the cost savings on which the payments will be based. The recommendations in the Executive Summary represented a change in cardiac catheterization procedures, for which the physicians were responsible and had liability exposure. The product standardization carried some increased liability risk for the physicians. It is not unreasonable for the physicians to receive compensation for the increased risk from the change in practice. Moreover, the payments to be made under the Arrangement represent portions of one year's worth of cost savings and are limited in amount (i.e., the aggregate cap), duration (i.e., the limited contract term), and scope (i.e., the total savings that can be achieved from the implementation of any one recommendation are limited). The payments under the Arrangement do not appear unreasonable, given, among other things, the nature of the actions required of the physicians to have implemented the twenty-one recommended actions, the specificity of the payment formula, and the cap on total remuneration to the Groups.[15] We caution that payments of 50% of cost savings in other arrangements, including multi-year arrangements or arrangements with generalized cost-savings formulae, could well lead to a different result.

In light of these circumstances and safeguards, the Arrangement poses a low risk of fraud or abuse under the anti-kickback statute.

[15] We are precluded by statute from opining on whether fair market value shall be or was paid for goods, services, or property. See 42 U.S.C. § 1320a-7d(b)(3)(A). While the Requestors have certified that the payments under the Arrangement are consistent with fair market value, we do not rely on that certification in this opinion, nor have we have made an independent fair market value assessment.

III. CONCLUSION

Notwithstanding the foregoing, we iterate our concerns regarding many arrangements between hospitals and physicians to share cost savings. Improperly designed or implemented arrangements risk adversely affecting patient care and could be vehicles to disguise payments for referrals. For example, an arrangement that cannot be adequately and accurately measured for quality of care would pose a high risk of fraud or abuse, as would one that rewards physicians based on overall cost savings without accountability for specific cost reduction measures. Moreover, arrangements structured so as to pose a heightened potential for patient steering and unfair competition would be considered suspect. In short, this opinion is predicated on the specific arrangement posed by the Requestors and is limited to that specific arrangement. Other apparently similar arrangements could raise different concerns and lead to a different result.

Based on the facts certified in your request for an advisory opinion and supplemental submissions, we conclude that: (i) the Arrangement could constitute an improper payment to induce the reduction or limitation of services pursuant to sections 1128A(b)(1)-(2) of the Act, but that the OIG would not impose sanctions on the Requestors in connection with the Arrangement; and (ii) the Arrangement could potentially generate prohibited remuneration under the anti-kickback statute, if the requisite intent to induce or reward referrals of Federal health care program business were present, but that the OIG would not impose administrative sanctions on the Requestors under sections 1128(b)(7) or 1128A(a)(7) of the Act (as those sections relate to the commission of acts described in section 1128B(b) of the Act) in connection with the Arrangement.

IV. LIMITATIONS

The limitations applicable to this opinion include the following:

- This advisory opinion is issued only to [names redacted], the requestors of this opinion. This advisory opinion has no application to, and cannot be relied upon by, any other individual or entity.

- This advisory opinion may not be introduced into evidence in any matter involving an entity or individual that is not a requestor to this opinion.

- This advisory opinion is applicable only to the statutory provisions specifically noted above. No opinion is expressed or implied herein with respect to the application of any other Federal, state, or local statute, rule, regulation, ordinance, or other law that may be applicable to the Arrangement, including, without limitation, the physician self-referral law, section 1877 of the Act.

- This advisory opinion will not bind or obligate any agency other than the U.S. Department of Health and Human Services.

- This advisory opinion is limited in scope to the specific arrangement described in this letter and has no applicability to other arrangements, even those that appear similar in nature or scope.

- No opinion is expressed herein regarding the liability of any party under the False Claims Act or other legal authorities for any improper billing, claims submission, cost reporting, or related conduct.

- This opinion is also subject to any additional limitations set forth at 42 C.F.R. Part 1008.

The OIG will not proceed against [names redacted], with respect to any action that is part of the Arrangement taken in good faith reliance upon this advisory opinion, as long as all of the material facts have been fully, completely, and accurately presented, and the Arrangement in practice comports with the information provided. The OIG reserves the right to reconsider the questions and issues raised in this advisory opinion and, where the public interest requires, rescind, modify, or terminate this opinion. In the event that this advisory opinion is modified or terminated, the OIG will not proceed against [names redacted], with respect to any action taken in good faith reliance upon this advisory opinion, where all of the relevant facts were fully, completely, and accurately presented, and where such action was promptly discontinued upon notification of the modification or termination of this advisory opinion. An advisory opinion may be rescinded only if the relevant and material facts have not been fully, completely, and accurately disclosed to the OIG.

Sincerely,

/Lewis Morris/

Lewis Morris
Chief Counsel to the Inspector General

[Appendix A and Distribution List redacted]